EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

Master File No. 2:12-MD-02327
MDL No. 2327
JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

_____/

Brenda Riddell
2:12-cv-00547
Dina Sanders Bennett
-cv-00497

Beverly Kivel
2:12-cv-00591
Barbara Kaiser
-cv-0887

Shirley Walker
2:12-cv-00873
Pamela Free
-cv-00423

SALIL KHANDWALA, M.D.

March 25, 2016

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The Deposition of SALIL KHANDWALA, M.D.,
Taken at 22731 Newman Street,
Dearborn, Michigan,
Commencing at 9:00 a.m.,
Friday, March 25, 2016,
Before Laurel A. Frogner, RMR, CRR, CSR-2495.

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(Exhibits attached to transcript)

Dearborn, Michigan

Friday, March 25, 2016

About 9:00 a.m.

SALIL KHANDWALA, M.D.,

having first been duly sworn, was examined and testified on his oath as follows:

EXAMINATION BY MR. WOOL:

Q. Good morning, Dr. Khandwala.

A. Good morning.

Q. We briefly met before, but formally I'm David Wool. I represent the plaintiffs in this case. Can you briefly state your name and spell your name for the record.

A. My name is Dr. Salil Khandwala, spelled S-a-l-i-l last name K-h-a-n-d-w-a-l-a.

Q. Okay. And is there any reason that you would be unable to answer truthfully or give complete answers this morning to any questions?

A. No.

Q. Okay. And you were sworn in, and you understand that you're under oath?

A. Yes.

ATTORNEY ON TELEPHONE: I'm sorry to interrupt. Is there any way to turn up the volume on the phone on your end at all?

(An off-the-record discussion was held.)

BY MR. WOOL:

Q. Doctor, I imagine that you've been deposed before, but just a couple of housekeeping things. Briefly, I'm going to ask questions. If your counsel, Mr. Walker, objects, he'll make an objection, and then after he finishes, then you can answer the question. And I'll do my best not to talk over you. I would appreciate if you'd do the same. And if any question is unclear or you don't understand anything, just ask me to clarify, and I'd be happy to do so. Does that make sense?

A. Yes.

Q. Okay. So I'm going to hand you what will be marked as Exhibit 1. This is your Notice of Deposition.

KHANDWALA DEPOSITION EXHIBIT NUMBER 1,
NOTICE OF DEPOSITION
WAS MARKED BY THE REPORTER
FOR IDENTIFICATION

BY MR. WOOL:

Q. Do you recognize this notice?

A. Yes.

Q. Okay. And in Exhibit 1 it requests that you bring some documents with you. Did you bring those documents with you today?

A. Yes.
Q. Okay. Did you bring all the documents?
A. All that I could get my hand on.
Q. And those are --
MR. WALKER: And let me just interrupt for a second and state on the record that we are expecting a thumb drive to be delivered approximately around 10:30 this morning that will contain a digital copy of all of his reliance materials. We have some of his materials printed in hard copy for counsel, but all of it will be on that flash drive.
BY MR. WOOL:
Q. Okay. Now, what did you bring with you today?
A. I got my CV, and I think it requested expense -- my CV and the itemized expense for preparation along with the thumb drive that he just mentioned.
Q. Okay. And the articles are all of your reliance materials?
A. Yes.
Q. Okay. Now, are there any opinions that you're offering today that are not included in your expert report?
A. It depends upon what you ask me.
Q. I guess --
A. I have a lot of knowledge, it's just not based upon a

few articles I can just furnish. So I have been gathering this knowledge over decades.

MR. WALKER: And let me just state that the doctor is prepared to offer opinions on the adequacy of the warnings in the IFU and any opinions pertaining to biocompatibility, specifically cytotoxicity or degradation, I don't believe those words are specifically referenced in the report, but he is prepared to offer opinions on those topics as well.

BY MR. WOOL:

Q. Okay. So there are opinions that you plan to offer at trial or in this litigation that are not referenced in your report?

A. That's correct.

Q. Okay. Any reason that those weren't included in your report?

A. They are actually included in the report, and just the words such as safe and effective, but that encompasses a lot, so if you ask me specifics about safe and effective, I can talk more about it. So, in other words, it's elaborating more on that, so it's a general word that I have used in the report because I could not make a 100-page report, but there are several things that I could discuss.

Q. So I guess when you're saying safe and effective, does that refer to warnings as well?
A. Yes.
Q. Okay. And does that refer specifically to the Instructions For Use?
A. It's everything, it could be referring to Instructions For Use, what the material is, the material science, and things like that.
Q. Now, let's go over your background briefly. Now, is this the first time you've been asked to give testimony or give opinions for a medical device company?
A. No.
Q. Okay. On how many other cases have you been hired as an expert?
A. I'd say about four or five, something in that ballpark.
Q. How many for transvaginal mesh manufacturers?
A. Four, it's the same, all were for transvaginal mesh.
MR. WALKER: And, counsel, just to clarify, are you asking if he's offered testimony or if he's just been retained?
BY MR. WOOL:
Q. If he has been retained as an expert.
MR. WALKER: Thank you.
MR. WOOL: Okay.

BY MR. WOOL:

Q. That leads me to my next question. So how many cases have you offered expert testimony in?

A. This would be my second case, or third case.

Q. Okay. And you have been deposed before?

A. Yes.

Q. Okay. Can I ask what manufacturers retained you as an expert?

A. It is -- actually it was not the manufacturer, but it was more the doctor's attorney, so I should take it back and say it was American Medical System, it was Elevate mesh, but I was defending the physician, and in the past it was Ethicon for a different case.

Q. So Ethicon and AMS?

A. Yes.

Q. And just so that I'm clear, the AMS case, was that a medical malpractice case?

A. Yes.

Q. And you were just defending the physician, you weren't representing the company at all?

A. That is correct.

Q. Okay. Now, when were you first contacted to be an expert for Ethicon in this litigation?

MR. WALKER: Just to clarify, are you talking

about the Wave 1 or any Ethicon case?

BY MR. WOOL:

Q. Any Ethicon case.

A. I think it was two years ago.

Q. Two years ago?

A. I think.

Q. So 2014?

A. Somewhere thereabouts.

Q. End of 2014, middle?

A. You know, I think it was summer, so maybe about June of 2014.

Q. And were you contacted again about being retained as an expert in the Wave 1 cases?

A. Yes.

Q. And when did that happen?

A. I think about four months ago.

Q. About four months ago, okay. And who contacted you?

A. I don't recall exactly, maybe it was Mr. Moriarty.

Q. And you don't remember exactly, that's just to the best of your recollection?

A. Yeah, most likely, most likely it's Mr. Moriarty, but I'm not sure exactly.

Q. Now, when did you first receive materials to review for these cases, the Wave 1 cases?

A. I think around that time they started coming in.
Q. Okay. Approximately how much time did you spend reviewing those materials?
A. I think I've mentioned in that handout there on your right side, the second page on the right side.
Q. Okay. Okay. And just approximate for the record, if you don't mind.
A. Could you please tell me. I don't recall exactly.
Q. Okay. It says 102 hours.
A. Okay, that's specific, then, 102 hours.
Q. So 102 hours reviewing materials, correct?
A. And I also did an independent medical examination on a patient.
Q. Okay, and four and a half hours of phone calls, correct?
A. That's correct.
Q. Okay. And your hourly rate is 500 an hour, correct?
A. Yes.
Q. Okay. And do you charge a specific amount or an additional amount for depositions?
A. Yes, I believe that's on that paper, too, I think it's $600 an hour; is that correct?
Q. I'm not seeing.
A. It's on the next page.
Q. Oh, okay.

A. If it doesn't state that, I think it's $600 an hour.
Q. Okay. I guess what I'm seeing on this case is $500 an hour for review. I don't think I see it.
A. For the dep -- okay.
Q. I don't think I see the $600 an hour. Okay. So approximately how much time did you spend preparing your general report?
A. Have I specified on that?
MR. WALKER: Can he look at that to refresh his recollection?
BY MR. WOOL:
Q. Yes.
A. Thank you. Six hours.
Q. Approximately six hours. Okay. And how much time did you spend meeting with defense counsel?
A. Four and a half hours on the phone and about 8 to 10 hours maybe.
Q. And does that invoice right there, does that contain all the time that you've spent recently in the past day or two preparing as well?
A. No, this is only up to March 8th.
Q. Okay. So following March 8th, approximately how much time have you spent reviewing?
A. You know, I haven't tabulated it, I've just been looking

at it. I've not totaled it up.

Q. What's your best sort of ballpark figure?

A. Maybe about 25 to 30 hours.

Q. Okay.

A. That's not just discussing but reviewing, you know, the documents and going over cases and things.

Q. Okay. And approximately how much time meeting with defense counsel?

A. About I would say 10 to 12 hours.

Q. 10 to 12 hours? Approximately how much time yesterday did you meet with Mr. Walker?

A. Three hours, because I was in surgeries in the morning, and then I met him in the afternoon.

Q. And approximately how much time this morning?

A. About an hour.

Q. Okay. And could I see that?

A. Sure.

Q. And so if I remember correctly, you've received approximately $54,000 total to date?

A. No.

Q. Or you've invoiced $54,000?

A. Yes.

Q. Excuse me. And is that for your general opinions or that's everything?

A. That's as mentioned on the right side, the right page, it's everything, it's broken down per case and also the general opinion.
Q. Okay.
A. As you can see, it's six hours at the bottom on the right page is six hours Prolift write-up.
Q. And that six hours for the Prolift write-up, that's the Prolift and the Prolift+M?
A. That's correct.
Q. Okay. Let's see, and have you prepared reports in any other mesh cases not Ethicon specific?
A. When I did the deposition for the AMS Elevate case I did look at their mesh.
Q. And for other depositions related to all mesh manufacturers, I believe you said you had testified once as an expert?
A. Yes.
Q. So one other deposition. Did you testify at that trial?
A. No.
Q. No? Okay. And so would it be fair to characterize your prior testimony as being exclusively for defendants?
A. Yes.
Q. Okay. Now, have you ever consulted for other mesh manufacturers?

A. Yes.
Q. What other manufacturers?
A. AMS, which is American Medical Systems, and changed its name to Astora, A-s-t-o-r-a, and Coloplast, C-o-l-o-p-l-a-s-t.
Q. Okay. And approximately how much compensation did you receive from AMS?
A. I'm sorry, I don't know the exact figure, it all depends upon -- I was a consultant for the product at the same time a clinical trial that I was doing.
Q. So if you had to guess the amount of income you received from --
A. I'm under oath, I just can't guess a number, I can't give --
Q. I'm just asking you to approximate.
A. Well, maybe about 8 to $10,000 at max for both the companies.
Q. Okay, so for each?
A. No, for both together, so about $4,000 per company I would say.
Q. Okay, about $4,000. Okay. And have you ever been a defendant in a case?
A. Yes.
Q. Tell me about that.

A. It was a case, actually I have two cases, one was an ovarian cyst case that I was involved with, and there was a potential complication with the ovarian cyst, and there was a gynecologic oncologist who had done the case with me and I had done a sling, but since I was involved in the case, but I was eventually dropped. The second case was a vaginal mesh case that, you know, they filed and they looked at the documents, and eventually they dropped the case.

Q. Okay. So in both cases the case was dropped?

A. Yes.

Q. Do you know if the case was dismissed or -- sorry, strike that. Do you know if a Judge dismissed the case on motion by defense counsel?

A. No. The first was I was -- I had nothing to do with the first case because I had just done the sling, it was an intra-abdominal case, so it was more of the GYN oncologist case, so that's why I was dropped from the case. The second, the case -- the attorneys didn't proceed.

Q. Okay. So they voluntarily dismissed you as a defendant?

A. Yes, so they just dropped the case completely.

Q. Okay. So let's go over your reliance list briefly and hand you -- I think you have a copy of that.

MR. WALKER: Do you have the one that we sent this week?

MR. WOOL: Yes, I was going to do both.

BY MR. WOOL:

Q. Let's mark this as 2 and this will be Exhibit 3.

KHANDWALA DEPOSITION EXHIBIT NUMBER 2,
RELIANCE LIST IN ADDITION TO MATERIALS
REFERENCED IN REPORT MDL WAVE 1
WAS MARKED BY THE REPORTER
FOR IDENTIFICATION

- - - - -

KHANDWALA DEPOSITION EXHIBIT NUMBER 3,
KHANDWALA SUPPLEMENTAL RELIANCE LIST
3.22.16 MEDICAL LITERATURE
WAS MARKED BY THE REPORTER
FOR IDENTIFICATION

BY MR. WOOL:

Q. Now, do both of those look like accurate copies of the reliance list that you've provided?

A. Yes.

Q. Okay. And does that include the whole of all the materials you relied on to make your report?

A. And as I told you, of course, a lot comes from my brain itself, you know, so I have read so much, so when I put

an article out, there is so much that comes out. So this is essentially the paper reference, as you may say, but there is a lot that could be just coming from within.

Q. Okay. So aside from your personal knowledge, does the reliance list in front of you contain all of the articles, studies that you've reviewed in drafting your general report?

A. That is correct.

Q. And forming your opinions?

A. Yes.

Q. Okay. Now, I just want to ask briefly because we received, I guess, an initial copy of the reliance list and then a supplemental copy. The original, I'm sorry, strike that. The supplemental copy contains everything that was in the original plus additional materials and studies, right?

A. That's right.

Q. Okay. So I'm not going to make you go through it, but there's nothing on the original reliance list that isn't in the supplemental copy that you gave us on I believe the 22nd?

A. That's correct.

Q. Okay. Now, I guess what was the story with the original

reliance list? I guess my question is why were the materials that were included on the second list not in the original list?

A. Just that when I looked at the list, I saw that I had done actually and reviewed much more than what was on the list, so I thought this is not a complete and a comprehensive list. I thought if I were to really give you a comprehensive list of all the potential articles that I've reviewed that this would be the case.

Q. Okay. So did you go back through and add those?

A. Yes. So when I looked at the list, I said yes, there is much more to this, and I said I looked at all my articles that I have reviewed, and then I just added it up and sent them over.

Q. Okay. And who provided you with the articles to review?

A. I had most of the articles, because I have been doing clinical trials for decades now, and I have been -- basically I have so many articles at my disposal. The only thing that I was provided was some of the Ethicon internal documents which obviously I had no -- I did not have it at my disposal.

Q. Okay. So Ethicon didn't provide you with any of the studies, any of the literature that you reviewed?

A. No.

MR. WALKER: And just to clarify, I want to be very clear, we have provided him with medical literature. What he's saying is he's already had it before we gave it to him if that makes sense.

BY MR. WOOL:

Q. Okay. So of that list, do you recall which of those articles are documents Ethicon provided you with?

A. The only thing that uniquely would stand out are the Ethicon documents, because the others -- it's a blurred vision, because it's obviously I have reviewed all these documents, because I have done papers on sling and vaginal mesh, I mean ongoingly even right now we are working on that, so I have all these documents and we stay up to speed especially since I'm a fellowship director.

Q. Okay. So I guess the internal documents that you reviewed, I guess the initial list has some Ethicon documents, is that an accurate statement?

A. I have to review it. Yes.

Q. Okay. And then the supplemental list has additional Ethicon documents?

A. Yes.

Q. So how did those get added to the list? Did you rely on those documents in formulating your report?

A. No, my report was basically formulated on my own knowledge and what I have done and experience over time, but this is just to get some of the information as to what was done and to understand what else has been around and the information out there. So it doesn't mean that it is part of it, it means that I have reviewed it, but that doesn't mean that if I have reviewed it, everything goes into my report. It is part of something that I have reviewed.

Q. So I guess my question is the additional Ethicon documents, you didn't rely on those in drafting your report?

A. Well, I can't tell you exactly what I relied on and what I didn't rely on. I drafted the report. It's not that I looked at the document and I basically verbatim took it down. So I reviewed the reports, and once I reviewed the information, then I formulated my own report, but, more importantly, my report is not based upon just this Ethicon documents, it's based upon my experience, and that's -- if you can see the report, it's literally, you know, that's what it spells out.

Q. Right, right, so you spoke a little bit quickly there, so just so I'm clear, did you rely on the additional Ethicon documents in drafting your report?

A. Yes.
Q. You did?
A. Yes.
Q. The ones that are --
A. I relied on all these documents to make my report.
Q. Okay, the ones that are contained in the supplemental reliance list?
A. That's correct yes.
Q. Exhibit 3. Okay. And Ethicon provided you with those documents?
A. Yes.
Q. Did you ask for any specific documents?
A. No.
Q. So they were just the ones that Ethicon gave you?
A. Yes.
Q. Now, did Ethicon provide you with an outline for your report?
A. No.
Q. Okay. So nobody asked you to say anything in particular?
A. No.
Q. Did you talk to any Ethicon employees in the process of writing your report?
A. No.

Q. Nobody? Talk to any other experts?
A. No.
Q. Any fellow physicians?
A. No.
Q. And are you familiar with all the documents and materials on your reliance list?
A. Yes.
Q. Okay. So let's go to your history in the industry. Now, are you under contract as a consultant for any -- for either Ethicon or let's just start with Ethicon, sorry, are you a consultant for Ethicon?
A. No.
Q. Okay. And have you been in the past?
A. Yes.
Q. Okay. Can you describe exactly what you did?
A. You know, that was long time back, probably it was 2004 to 2008, but if I were to vaguely remember then, it was, I was a proctor for the TVT products and the Prolift and Prolift+M. I was also doing an investigator initiated study, so I don't think that is industry typically, though it was sponsored by Ethicon, but it was my own clinical trial on the TVT Secure. And I was one of the principal investigators for one of the mesh studies called Prosima, and I think I was also -- that's the

main thing.
Q. Okay. Anything else --
A. No.
Q. -- for consulting?
A. No.
Q. Okay. You said you were a proctor. So what exactly is that?
A. A proctor is where I have, you know, physicians, could be gynecologists or urologists who come to the operating room and observe me doing a surgical procedure or I go to their center and guide them in the operation or I teach them at a cadaver course. So it could be a center with the cadaver courses and the theory, and then there is practical hands-on training.
Q. Okay. And in this sort of teaching you're exclusively training other physicians?
A. That's correct.
Q. Okay. Approximately how much compensation did you receive?
A. You know, I can't -- this is way back. I don't think I -- I think probably -- I don't know if it happened after 2006, because the only thing that -- if I remember, and it's very vague, what I remember is that after that it was just my TVT-S in-office clinical trial

which I had the investigator initiated study which was sponsored by Ethicon. That is the only reimbursement that I got.

Q. So to be clear, you didn't get any reimbursement for your work as a proctor?

A. No, I did.

Q. Oh, you did?

A. But that is way back. This is total recall -- I mean I can't remember what happened 10 years ago.

Q. So you don't have a recollection of how much you were paid for this?

A. No.

Q. Do you have an approximation, any guess?

A. If I were to say it, maybe about $15,000, $20,000, somewhere in that ballpark.

Q. Okay. And was it based on kind of a contract? Was it per -- was it per, I guess, teaching opportunity?

A. Yeah, it was two types. One was I remember there was an annual contract, and they had to have the annual contracts, and the second was based upon each type when physicians came to learn from me in the operating room or if I went to teach a cadaver course.

Q. Okay. And for your work as a proctor you used Ethicon products exclusively?

A. Yes.
Q. What products?
A. The entire line, the TVT family and the vaginal mesh family.
Q. And that included the Prolift?
A. Yes.
Q. And I know that you gave an answer on all of your consulting, but in addition to a proctor, you said you also served in what other capacities?
A. I don't think I said.
Q. So aside from your work as a proctor for Ethicon --
A. Yes.
Q. -- what other, I guess, consulting or I guess paid positions did you have?
A. I was an investigator in one of their mesh studies, one of the principal investigators in the TVT Secure clinical trial, so we initially started that clinical trials.
Q. And what sort of work does that entail as an investigator?
A. So as the investigator, we basically started getting -- understanding the product and seeing how the product design was, then figuring it out, how it would be applicable in women's health from the standpoint of

urinary incontinence, and then we were initial group who started doing the clinical study in humans with the TVT Secure.

Q. Okay. Now, have you ever been a key opinion leader for Ethicon?

A. Yes.

Q. Okay. And when was that?

A. That was around the time when the TVT Secure monogram was coming out, and we tried to put the information together about what are the pearls for proper technique for this particular surgical procedure.

Q. So approximately what time frame are we talking about?

A. Maybe 2006, 2007.

Q. '06 to '07?

A. Somewhere in that.

Q. And that was the only period that you served as a key opinion leader?

A. Yeah.

Q. And were you compensated for that?

A. Probably I must have, because I don't think that they would do --

Q. Any approximation on how much you were compensated?

A. No, there was just one meeting probably, a couple of meetings.

Q. Just a couple meetings?
A. Yeah.
Q. And what specifically were you asked to do for Ethicon in those meetings?
A. So one -- so in that particular meeting, which was on the TVT Secure, they wanted to gain my experience as to why were physicians noticing problems and, you know, some issues, and how is a better way to manage this with the TVT Secure. And so we came up with the entire pearls as to what exactly the steps should be, so this was a group of physicians that came up so as to teach the new group of doctors trying to get into this so they have the right steps that they could follow. The same thing was being done at something called the summit meetings which I would attend. These were annual meetings by Ethicon, and they'll get physicians out so that we could brainstorm on certain topics. At these meetings then I would lead a small group session mainly on the TVT Secure or sometimes it could be on the Prolift+M.
Q. So what problems, I guess, were they hoping you could help them address?
A. There was a problem with the TVT-S versus the TVT-U, something about that, so how the physicians were not

understanding how to place it, so it was a different concept change. See, when you're going from a transobturator long sling to a mini sling, this was the first time that mini slings were being performed. So most physicians were used to doing the long slings. And what they were -- they were not realizing in there because of their experience how they were operating is the classic thing is to leave a gap between the sling and the urethra with the long slings. And it was becoming more and more evident to the initial investigators that that gap should not be left. So if the TVT Secure was put properly and snug against the urethra, the success improved. So this is what we wanted to highlight to the physicians and make them aware that it is not the problem of the device, it's not the problem of the sling. It's a problem of proper placement and approximation under the urethra, and that is critical for the success of TVT Secure. So what I was doing is we were enjoying very good results with this, and that's why they wanted my opinion to see what is it that you are doing. How come you are having this results, and how can we now translate this to everybody else who's starting to learn this. It's a different thought process. That's what they wanted to come up

with a different thought process that do not -- so just to give you a once quick example is the TVT cannot be too loose whereas a TVT Secure cannot be too tight.

Q. Now, did any of the problems deal with the Prolift?

A. No, my main thing was on the -- I mean it's not a problem of the device, either, there's a lot of TVT Secure device and the Prolift device.

Q. So what I'm asking is for your work as a key opinion leader, did any of that involve the Prolift or the Prolift+M.

A. No.

Q. None of it?

A. No.

Q. Now, you also worked as a key opinion leader for summit meetings, you said?

A. Yes.

Q. Okay. And what sort of topics would you discuss with other physicians at those meetings?

A. The entire -- both families, the TVT group of families and, also, the vaginal mesh family.

Q. Okay. And any problems that people were having with the Prolift or the Prolift+M --

A. No.

Q. -- at those meetings?

A. No. In fact, they were very happy with the devices.
Q. Okay. So at no point in any of your work as a key opinion leader at these summits did you discuss the Prolift or the Prolift+M?
A. No, we discussed it. I didn't say we did not discuss. I said we discussed it but there were no problems.
Q. Okay. There were no problems that other physicians were having?
A. That's correct.
Q. Okay.
A. In fact, if you don't mind me interrupting, when they came up with the new device which was a trocarless device when the Prosima came out, there was a major uproar in the group of physicians who were out there because they were so happy with the Prolift and the Prolift+M and the trocar based technique, they did not want to go to an trocarless system.
Q. Have you ever been involved in the preparation of an IFU?
A. No.
Q. Drafting of an IFU?
A. No.
Q. Have you ever been hired as a consultant to draft an IFU?

A. No.
Q. Has any medical device company ever retained you to help them draft Instructions For Use?
A. No.
Q. Have you ever been approached by a medical device company for your opinion on warnings?
A. Prior to launch?
Q. Yes, prior to launch.
MR. WALKER: I'm going to object to form.
THE WITNESS: No.
BY MR. WOOL:
Q. No? Have you ever been a consultant for the FDA?
A. No.
Q. Ever been employed by the FDA?
A. No.
Q. Received any compensation from the FDA?
A. No.
Q. Have you ever served on an FDA advisory board?
A. No.
Q. Have you ever corresponded with the FDA about your opinions related to pelvic mesh?
A. Yes.
Q. Tell me about that.
A. It was a report that we wrote out, it was authored by

Myles Murphy, and it was about after the FDA advisory came out in 2011 we came together and put up a report, so I was one of the physicians involved in that report.

Q. Okay. And very briefly, that report disagreed with the FDA's opinion?

MR. WALKER: Object to form.

THE WITNESS: Not entirely, but it did disagree on several points.

BY MR. WOOL:

Q. Okay. Let's see now, have you ever corresponded with any society about your opinions related to pelvic mesh?

A. Can you repeat the question, please?

Q. Have you ever corresponded with any medical society regarding your opinions related to pelvic mesh?

A. No.

Q. Are you a member of AUGS?

A. Yes, that's American Urogynecology Society.

Q. Right. And you've never corresponded with them related to your opinions on mesh?

A. That is correct.

Q. Okay. You're a member of -- I'm going to call it AUGS. Do you have any sort of leadership position within that society?

A. No.

Q. Have you ever served in any sort of leadership role within that society?
A. No.
Q. Okay. Sorry, I'm just looking for your CV.
A. It's in the binder I gave you.
MR. WALKER: It's in the bottom of what you're holding.
BY MR. WOOL:
Q. Okay. So I'm going to hand you what will be marked as Exhibit 4.
KHANDWALA DEPOSITION EXHIBIT NUMBER 4,
SALIL KHANDWALA, MD FPMRS FACOG -
CURRICULUM VITAE
WAS MARKED BY THE REPORTER
FOR IDENTIFICATION
BY MR. WOOL:
Q. And I assume that this is the same CV that you provided me with today?
A. Yes.
Q. Is that correct? Okay. And everything is up to date?
A. Very likely.
Q. Very likely. Do you see anything that --
A. Can I see my --
Q. (Handing.)

A. I think you should go by this, couple of articles that I've put in this CV that are relevant, just a couple of articles --

MR. WALKER: Counsel, I'll note that there are redactions on what you offered as Exhibit 4, I believe, at the very top so --

MR. WOOL: So this will be redacted as well.

MR. WALKER: Yeah, I'd just like to make it clear we'll need to redact the CV accordingly.

MR. WOOL: And would you pass me that blue folder again.

BY MR. WOOL:

Q. Okay, because I haven't had a chance to review this, what updates are contained in this version that --

A. I think there's a paper -- I'm not -- you know, it's positioned the first in one of my papers and publications, so I don't know if it was in the other CV, the first paper, but maybe it's there, but maybe it's the organization was not there.

Q. So does it reflect any new research that you're involved with that wasn't involved in the -- that wasn't included in the first copy?

A. No, published research, research but it's not published yet.

Q. Okay. Let's see now, you went to medical school at the University of Bombay?
A. That's correct.
Q. And then you did your residency where? I'm sorry, where did you complete your residency?
A. Well, I did it at -- mainly initially I did it in Bombay, and then I did an OB-GYN residency at Greater Baltimore Medical Center in Baltimore.
Q. And is that where you did your fellowship as well?
A. I did two fellowships. I did a fellowship in France in laparoscopic surgery, fellowship there in Clermont Ferrand, C-l-e-r-m-o-n-t F-e-r-r-a-n-d, and second fellowship I did at Greater Baltimore Medical Center and University of Maryland in female pelvic medicine reconstructive surgery, FPMRS.
Q. Did you use mesh in your fellowship?
A. Yes.
Q. Okay. Now, who instructed you on the use of mesh for pelvic organ prolapse, for the treatment of pelvic organ prolapse?
A. I started using mesh even when I was a resident in my second year with the gynecologists who were practicing there, so many of them were using it for abdominal

sacrocolpopexy. And we then started using mesh as the sling for the retro pubic TVT procedure.

Q. Okay. And who instructed you how to perform these procedures?

A. Dr. Alfred Bent, who was my fellowship director.

Q. And what mesh did you use at that time, do you recall?

A. I believe it was the Gynemesh, but I don't know exactly what was it, because I was a resident at the time. That was the mesh for abdominal sacrocolpopexy. Then for the TVT it was the TVT mesh.

Q. Okay. And did you learn nonmesh surgical techniques at that time as well?

A. Most of the techniques at that time were non-mesh, so yes, I was very familiar with non-mesh.

Q. Okay. And going forward I'm going to refer to those as traditional surgical techniques or techniques with native tissue repairs. Does that seem like a fair characterization?

A. I don't think so, because traditional, I don't know what that means. You can say native tissue repair, I'm fine with that.

Q. Okay, so native tissue repairs, we'll use that term. And who instructed you or who taught you the native tissue repair techniques?

A. Many of my gynecology faculty and, also, Dr. Bent, who was the fellowship director.
Q. So at that time, I guess, did Dr. Bent, B-e-n-t?
A. Yes.
Q. Did he have a preference for mesh or native tissue repairs?
A. It depended upon the case. If the case was an extremely large vaginal prolapse, then he would do an abdominal sacrocolpopexy procedure, and that's what we did. If it was a vaginal procedure he could -- he thought he could get away with a vaginal case, then he would do a native tissue repair. It all depended upon how the extent of the prolapse was, the recurrence of the prolapse, had the patient had a prior prolapse surgery, so a lot of factors went into making in that decision.
Q. So if you had to guess during your fellowship as to the percentage of each surgery, either native tissue repair or mesh surgery, which one did you do more frequently?
A. That depends upon the indication. So we're talking about two things. Number one, if you're talking about incontinence, then I would say that during my fellowship that spanned 2000-2002, in that period of time it was predominantly we were doing laparoscopic Burch colposuspensions. Then that's when the TVT was sort of

coming into being. And then from the point of view of vaginal prolapse surgery, it completely depended upon the case. So I can't tell you exactly what, I mean again so far back, I can't tell you what we were doing predominantly for. So the indication changed, so if you asked me from the standpoint of indication if a woman had a recurrent vaginal vault prolapse, what would be the best case, and abdominal sacrocolpopexy with mesh would be the preferred operation for that case. So I can't generalize and say that, you know, which one we did more or less of, it's based upon, you know, the indication, the reason why we were doing it.

Q. So you can't give me an approximation for pelvic organ prolapse?

A. Correct.

Q. So describe your training on how to implant transvaginal mesh.

A. So I was doing a lot of vaginal reconstructive surgery, and my expertise was in vaginal reconstructive procedures right my residency in India to my training in France to my training and doing my residency in the U.S. So having done that much, I was very familiar with the vaginal anatomy. As I was doing the vaginal native tissue repairs, I was very frustrated by the outcomes I

was getting. We were having a lot of failures, and I was working very hard to do the best I could, and I knew something is not right, there is something that has to be done to improve the success for these failures.

Just about that time there was talk about vaginal augmentation surgery. All we had at that time was abdominal sacrocolpopexy, which used a mesh, so you would take a sheet of mesh, cut it to size, and do it. So I've been using mesh since 1992 or '93, but this, when we started doing vaginally, and then I realized that augmentation surgery is something which is going to be beneficial to my patients because they were just failing, that's when I realized that, I got into vaginal augmentation surgery with mesh.

Q. So, Doctor, I don't think that we really got a clear answer on that question. Okay. So specifically training for the implantation of vaginal mesh, not the entire anatomy, when did that occur predominantly?

A. It was around the time when the IVS tunneler was launched in 2002, I believe, somewhere in thereabouts, 2002, 2003.

Q. Okay.

A. But it is -- the reason why I'm saying that is because it is not -- it's mesh -- the technique is not -- the

most important thing is the dissection and, I'm sorry, the anatomy, and then you're putting the mesh in, I was doing it from above, anyway, so now we got the ability to do it from below, and that's when, the device when it came out, it was around 2002, 2003 when I started doing the, you know, transgluteal passages for prolapse.

Q. And how were you trained to perform that procedure?

A. I had gone to a cadaver course, and I did cadaver passes and I -- someone had come to proctor me at my site, you know, when I was doing the first case, first couple of cases, and then I started doing them on my own, because the most -- 95 percent of the thing doesn't change, the dissection, that's the key. Whether you use mesh or you do not use mesh, the dissection is very similar, it doesn't change that. All that changes is what you're going to do there. Are you going to put in a piece there or are you going to put the tissues together?

The only other difference was passage of these Trocars, which is the only additional thing I had to learn, which is truly about 5 percent of the entire surgical procedure.

Q. Okay. So this was an academic course in roughly the 2002 to 2003 time period which is where you learned?

A. Correct.

Q. Okay. And then as you started to perform the procedures, was anybody ever guiding you?
A. So now this we're talking about the vaginal mesh for prolapse?
Q. Yes.
A. No, then I was just monitoring my own cases.
Q. Okay. And this course that you took in '02 to '03, approximately -- strike that. Let's see, so you currently -- do you currently hold any academic positions?
A. Yes.
Q. Where?
A. At Wayne State University, I am associate professor at Wayne State University in the Department of Obstetrics and Gynecology.
Q. And do you receive a salary from Wayne State?
A. Yes.
Q. Okay. Approximately how much?
A. It is a very nominal salary because I'm an associate professor, it is to teach the residents. I think it is about $10,000 per year.
Q. And what are your responsibilities in teaching the residents?
A. Make them aware of the science and the medicine of

female pelvic medicine and reconstructive surgery or FPMRS. So they rotate with me. There are about 10 residents there. Each resident rotates with me for a month and they follow me, they come to the office, they see patients with me and with my fellow, and then they go to the hospital to do surgical cases with me.

Q. Okay. And I guess when you're training them, is it exclusive to, I guess, watching you perform surgery or are you doing cadaver training as well?

A. For them it is more to make them aware of the entire field. So what we're focusing now is the surgical procedures is just a technique, it's a very small piece of this entire field. This field is much more than just doing a surgical procedure. The biggest thing is when do you do this or what reason, who is the right patient? And that's what they'll learn with me in the office. So they come with me in the office, they understand the pathophysiology, they understand the science behind the pathophysiology, and once they understand all that, then they see the surgical technique. So they do the whole thing.

Q. Now, do you ever teach them anything related to the removal of mesh?

A. Well, I hardly have any of those cases, but even if I

had, they would just see with me as I'm placing it and if I am removing it. I've never had to remove an entire mesh.

Q. You never had to explant an entire mesh?

A. Never.

Q. Never? Okay. But you do have to remove portions of mesh, correct?

A. I've had to do it a few cases.

Q. All right, a few cases. Are they your own cases?

A. Yes.

Q. Okay. Have you ever had to remove mesh from another -- from a patient that started with another physician?

A. Very few.

Q. Very few? Approximately how many?

A. Maybe about four or five.

Q. Four or five?

MR. WALKER: Can I just ask for clarification? Are you asking about mesh in general from any manufacturer or --

MR. WOOL: From any manufacturer.

THE WITNESS: Yeah, I'd like to clarify that, too. I'm talking about mesh removal not only from any manufacturer and any manufacturer but also for any procedure, which is not just prolapse but also

incontinence.

BY MR. WOOL:

Q. Okay. So approximately how much removal from prolapse?

MR. WALKER: Again, are you talking about any manufacturer?

MR. WOOL: Any manufacturer, yes.

THE WITNESS: Maybe two. It's usually the slings that I have had to modify.

BY MR. WOOL:

Q. Okay. And so what types of patients do you typically see?

A. General in my practice?

Q. Yes.

A. It's -- I see predominantly patients for female pelvic medicine reconstructive surgery, which is patients with urinary symptoms, could be urgency, frequency, leakage of urine, whether urgency leakage or cough-associated leakage, vaginal pain, vaginal prolapse, accidental bowel leakage, and female sexual dysfunction.

Q. Now, when somebody presents to you with pelvic organ prolapse, what factors are you looking at to see whether or not they might be an appropriate candidate for a mesh surgery?

A. First of all, the patient has to be complaining of the

presence of a bulge, so when she comes to me and she says that this is a bulge, it's bothersome and it's coming down and this bothers me, so the bulge itself has to be a bothersome factor to the patient. The way we do in our practice is we give our patients what is known as validated questionnaires. So they fill out these validated questionnaires. One of the validated questionnaires I give them is something called PFDI-20, Pelvic Floor Distress Inventory short form 20, and in that form they basically put out what are the symptoms, and it goes over aspects of bowel, aspects about the bladder, and aspects about the vaginal prolapse. So when they do that form, then they also have a couple of other forms they fill out called PFIQ, which is a quality of life questionnaire for Pelvic Floor and Incontinence Questionnaire and some urinary incontinence questionnaire. Once they fill out, we get a very good idea as to what is her main complaint, what is she mainly bothered by? Is it pain? Is it discomfort? Is it leakage? Is it urinary inability to empty? Or is it a persistence of vaginal bulge? Once we review those questionnaires, then we go in and talk to the patient and go over those questionnaires with the patient and then try to clarify as to what is going on.

Following that we do an examination and we do a very thorough examination lying down, sitting and standing, and we may take a video of the prolapse if it is there, and we review the video with the patient and say this is what we found, this is -- are you complaining about this? What is your main complaint? So the key thing here is to correlate and make the patient understand that if she has a bulge, is that what she's bothered by, the presence of the bulge?

Then there are other factors that come up in the validated questionnaire and the other part of the history form such as has she had any prior surgeries done for this problem? Is she a smoker? What is her weight? Does she have any risks such as diabetes that could affect tissue healing? How long has this prolapse been? What is the texture of this prolapse? Is it thin walled? Is she menopausal? Is she on estrogen? Does she have associated complaints such as bladder complaints, bowel complaints? All that goes into play to decide what do I need to do? More importantly, I also look at whether she has a uterus.

If she has a uterovaginal prolapse, which is significant, what we do at our center is we do not take the uterus out. We do uterine preservation operation.

So that is very important in my decision whether I am going to use mesh or not, uterine preservation, because that is what we strongly believe in, and that's a paper that we published, and it's part of my report and, also, a paper that we are actually working on about to be published with the Exair, E-x-a-i-r, mesh from Coloplast.

Q. So depending on all these factors, somebody may or may not be a good candidate for mesh?

A. That is correct.

Q. And so what are some of the other treatment options that you offer?

A. The most important option I offer them is to do nothing. So if they're coming in, they're not bothered by this, I tell them don't do anything about this and just let's see how it goes. Many a times patients just need reassurance. They think that sometimes they do come into my office and the gynecologist sees a bulge and says, hey, go to the specialist and get it taken care of. They come here, we go over these validated forms, we realize that she's really not bothered by this bulge and she's here because her doctor sent her. Tell them there's nothing to do. That's very important, to do nothing.

Number two is to do something called pelvic floor therapy, which is improving the tone of the pelvic floor muscles, and in mild degrees of prolapse it works very well to improve that, you know, so that they do not have to go for an operation in the future or it doesn't worsen.

Third, we talk about pessary, which is a device -- p-e-s-s-a-r-y -- which is inserted into the vagina to hold the bulge inside. That's the third thing we talk and discuss with patients.

Fourth, we talk about if we then went -- go into surgery, after having discussed expected management, pelvic floor therapy, pessary management, then we will discuss surgery, we then explain to the patient about what is the prolapse that she's having and what could be done about that and the different options, whether she goes in for native tissue repair or whether she goes in for vaginal mesh augmentation surgery.

Q. Okay. So you offer native tissue repair to your patients?

A. Yes.

Q. So what are the factors that would lead you to direct somebody, or direct a patient towards native tissue repair?

MR. WALKER: Are you talking about for prolapse?

MR. WOOL: For prolapse, yes, this entire question is about prolapse.

THE WITNESS: Well, it depends upon the extent of the bulge, and many a times if the patient has a bulge which is not that significant for recurrence, let's say if it is a Stage 2 vaginal bulge and it's not really coming out but she is bothered by this and she says I just don't like this, I understand it's not coming out, you know, I know that it's not outside my body, but it is right there, so I just don't want it to be there, so in that patient, you know, I would tell her that listen, I'm going -- in the intervention I talk to them about vaginal mesh augmentation, also, when I go in for surgery, I say I'm going to go into the OR, and in the OR I will decide what happens. Most likely you will not need mesh, you know, if I don't have to put it, I won't put it, whatever little or more, whatever that is depends upon the surgical outcome. What I tell her is that what my goal as your physician is to give you the best chance at success at this first attempt. That's my job. So when I go in and I open up the vagina and I find that the tissue is completely attenuated, there's

nothing there, then I would augment it. You never know, until you actually get in, you never know. So I give patients what options, and I make them understand why I would decide one versus the other.

Q. Right, so you said if they were presenting with Stage 2 prolapse. Any other factors that you would consider in directing somebody towards native tissue repair?

A. That's the main -- well, it depends upon what I find, but that's the main thing. If a larger prolapse, you know -- see, the typical operation that I perform, and if you look at my literature, also, most of the operations I perform are for stage 3 to stage 4 vaginal prolapses where there is a significant bulge that's coming out, especially uterovaginal prolapse. You know, then I would not do native tissue repair unless it -- I mean native tissue repair for a large uterovaginal prolapse, that requires hysteropexy, that means where the uterus is kept inside, hysteropexy, where the uterus is kept in inside, fails. There are papers published by Dietz and Lynd, you know, that if it's stage 3 or stage 4, there's a 70 to 80 percent chance that vaginal native tissue hysteropexy will fail. What we believe strongly is to keep the uterus, so that is our number one thing. So if the patient has large uterovaginal prolapse, I

will almost always recommend mesh surgery.

BY MR. WOOL:

Q. Okay. So in addition to Stage 2 or better, any patient-specific factors, obesity, if they're a smoker, anything else that weighs in on your decision?

A. Yeah, just as I mentioned earlier, so those -- I mean all these -- there are several, several factors I look at right from what is their age, is she postmenopausal, is she on estrogen, how is her vaginal anatomy, what is the -- is it thinned out, is it atrophic, does she have decubitus ulcers of the prolapse, then does she have recurrence, is it a first time or is it a recurrence, weight absolutely because BMI would have an influence on the success. Ultimately what I believe in doing is that I want to go in and do this once and for all. I do not want this patient to come back. I don't want her -- to take her back to the OR nor should she be going back to the OR. So what in my hands and in my experience is the best treatment for this patient, is the ultimate judgment. So there are many, many factors. Sitting across the table from you I can't just say, hey, this is just one thing or two things. There are so many factors that go into play, and it's so much individually tailored. Now, you may say, okay, your pant size is 30

to 32, but until you actually try the pant, you don't know if it's going to fit you.

Q. Right. And so you said in your last answer that one of the main things you're looking for is trying to come up with a treatment solution that will not send them back to the operating room, is that --

A. That's my main goal, yes.

Q. Okay. So what percentage of your practice involves pelvic organ prolapse?

A. Probably about 50 to 55 percent.

Q. And what mesh products do you use for treatment of prolapse?

A. I use the Elevate, E-l-e-v-a-t-e, which is by Astora, and I use the -- I used to use Exair, E-x-a-i-r. It's not on the market anymore.

Q. And you started with the IVS tunneler?

A. Yes.

Q. Okay. And then you switched to the Prolift?

A. Yes.

Q. Now, why did you make the switch?

A. Because the IVS tunneler, it is a very good concept, you know, where you are now figuring a way out to attach the Gynemesh is what was being used, the Gynemesh to the sacrospinous ligaments, but the IVS tunneler is a sharp

metallic rod, and you have to turn it around and bring it in your face to feed the mesh loop in, you know, so that's a very -- it's very hard to have a metal rod which is nonflexible to turn and bring towards you.

What Prolift did is it was similar concept but it basically penetrated the ligament and the moment it penetrated the ligament, the needle just stayed there, and then you threaded the mesh retrieval loop from there to retrieve the arms of the mesh. That was phenomenal because that made a big difference because that decreased the amount of tissue trauma that was being brought about by the tunneler.

Q. So it was the process that led to your change in your practice?

A. Yes.

Q. Okay. Not the -- you didn't assess any differences in the mesh itself?

A. I believe the mesh was the same. I think the mesh that was used with the IVS tunneler was the Gynemesh PS.

Q. Okay. And then you moved from the Prolift to the Prolift+M?

A. That's correct.

Q. Now, why did you make that change?

A. That's a very good point, you know, I can still vividly

remember why I would do that, you know, because I was enjoying, as evident in my study of 315 patients, I was enjoying great results with the Prolift, and I thought should I change something that I'm doing good with? You know, and then I looked at just the basic concepts, and I said, well, what if -- you know, the typical concept in medicine is do -- use -- you know, the risk balance, so what if I can get the lowest dose of a drug possible to get that effect, because the lower the dose, maybe then she will not have possible side effects. So maybe if you have a mesh that partly melts away, then maybe it could have a better effect. Maybe that, you know, then the factor was that it has this lateral stability and longitudinal flexibility and stretchability, so that may allow the bladder to distend more, the rectum to distend more, so theoretically, it made sense, from the engineering standpoint.

Q. So it was based on a theoretical proposition?

A. I had nothing against Prolift, I loved Prolift. It did a fantastic thing. The only reason to switch was this possible theory that could it -- could you -- and it's good to advance, you know, medical changes -- changes are sometimes good, so you never know what it is going to bring, and if it looked at, yes, this is something

that could be better, maybe from whatever reason, maybe now we're getting success with -- Prolift was very good, but what if we could get even better, for whatever reason, you know, from something which is theoretical.

Q. And this decision was based on the fact that the M has --

A. Monocryl.

Q. Monocryl --

MR. WALKER: Let him finish his question.

BY MR. WOOL:

Q. So that was the overriding factor that led to your decision to switch?

A. It was the -- it was Monocryl, but, more importantly, what was described is that it maintained its lateral strength, so that's where it's anchored, the lateral strength, but it allows more of longitudinal flexibility. So what that meant is theoretically how could this be important? One, as the bladder is distending, as the bladder is filling, if you have a mesh that could stretch longitudinally, it may allow it to fill more. The rectum, same thing, intercourse, because typical, you know, Master's and Johnson's theory about intercourse and foreplay is that there is ballooning of the vagina. So if you have a mesh that

has longitudinal flexibility, then theoretically, you know, it makes sense that during intercourse it would be more flexible and may therefore yield more possibly.

Q. And so we're still talking about your decision to switch from the Prolift to the Prolift+M. So what data was available to you at the time that the M had greater lateral strength?

A. It was just the experiment, the information from the engineers.

Q. From the engineers?

A. Yeah.

Q. From Ethicon's engineers?

A. From Ethicon's engineers.

Q. Okay. And the Prolift and the Prolift+M are no longer on the market, correct?

A. That is correct.

Q. Okay. And when they were taken off --

A. Can I take that back. The Prolift and Prolift+M as a device is not on the market, but the mesh is still around.

Q. Right. Okay, and then from there you switched to what device?

A. I switched temporarily to Elevate, and then I switched to Exair. The reason why I went with Exair was --

E-x-a-i-r was made by Coloplast, it was a similar technique as the Prolift, almost identical, and, you know, since this was not available and literally I mean I still remember that when we initially made the pass, I made my first two passes and then just I handed it over to my fellow, and my fellow started doing it because he was doing the Prolift+M already so it was nothing different, so I didn't even have to do more than two passes because it was almost identical to the +M technique.

BY MR. WOOL:

Q. So approximately how many procedures did you use for the Prolift?

A. About -- Prolift I would say about between 350 to 400, in the 400 vicinity, 315 is what we gathered the data on.

Q. Okay. And the +M?

A. +M I would say something similar. We did a long-term results on 250 cases of consecutive use, but then there are a lot of other cases that were not part of that consecutive use paper that was published.

Q. Okay. And do you think that those numbers are typical for a urogynecologist implanting mesh for pelvic organ prolapse?

MR. WALKER: Object to form.

THE WITNESS: I don't know, I don't know what others do. I'm sorry. I can't comment on others.

BY MR. WOOL:

Q. I guess do you think that that is a high number for somebody in the field?

MR. WALKER: Object to form.

THE WITNESS: It is an appropriate number for someone who sees a proper pathology. So, you know, if someone is seeing -- most urogynecologists like me are referral centers, so we get patients who have these large prolapses that come into our lap, so I don't get Stage 2 prolapses, I'm more -- most of my prolapses are stage 3 or stage 4. I mean the other day I did a patient that was 18 centimeters outside the vagina, so, you know, these are the prolapses that usually come to a referral center. So when I'm looking at it from a referral center, of course my statistics -- I'm going to be biased because I'm going to be banking more on vaginal mesh augmentation because I see more, but I don't know, you know, what others are doing, you know, what other physicians do, but typically from what I know is that most referral centers will really get all the bad cases or the large cases.

BY MR. WOOL:

Q. And that -- and you are a referral center, your practice is a referral center, correct?

A. Yes.

Q. Okay. And --

MR. WALKER: David, we've been going a little over an hour --

MR. WOOL: Yeah, we can go off the record.

(A recess was taken from 10:10 a.m. to 10:21 a.m.)

MR. WALKER: Before you start, I want to put on the record that we received a flash drive from FedEx during our break, and that flash drive contains Dr. Khandwala's reliance materials, and I have provided that to Plaintiff's Counsel.

MR. WOOL: Okay.

BY MR. WOOL:

Q. Okay, Doctor, so I just asked you about the number of Prolift and Prolift+M procedures that you had performed. Prior to switching to the Prolift, approximately how many IVS procedures?

A. You know, I can't recall that, that was probably 2002, 2003, I have no idea.

Q. You think in the hundreds?

A. No, I'd probably say about maybe 20, 25, in that ballpark, because from what I remember, as soon as the IVS tunneler came out, Prolift was in the works, and it came out soon thereafter.

Q. Okay. And prior to the tunneler, approximately how many surgeries had you performed using mesh for the treatment of pelvic organ prolapse?

MR. WALKER: Are you talking about transvaginal mesh or --

MR. WOOL: Yes, any manufacturer.

THE WITNESS: Well, there was -- we didn't have any transvaginal meshes at that time.

BY MR. WOOL:

Q. Okay. Any other meshes, Gynemesh?

A. I don't think I did any patch meshes, so, no, I was just doing fascia repair, native tissue repair.

MR. WALKER: I was just making a distinction between the vaginal and abdominal approach.

MR. WOOL: Right.

THE WITNESS: Abdominal, of course, we would --

BY MR. WOOL:

Q. Okay. And I'm sorry if I asked you this question before, or actually, no, I'm sorry, strike that. Okay.

So approximately how many patients have you treated with mesh erosion?

MR. WALKER: Object to form.

THE WITNESS: What do you define by erosion?

BY MR. WOOL:

Q. I guess how would you define erosion medically and then --

A. Well, it's a very -- the terminology has been very loosely used in literature to date. Mesh erosion has been sometimes labeled as in the vagina, in the neighboring viscus. The way now and the new nomenclature states that words like extrusion should not be used. Erosion is where the mesh breaks into a neighboring viscus such as the bladder or the bowel. If that's the question you're asking me, how many mesh erosions have you had, I have not had a single.

Q. You haven't treated a single patient for an erosion?

A. I have not treated a single --

MR. WALKER: Object to form.

THE WITNESS: Personally I have not treated a patient with vaginal mesh erosion the way I defined it.

BY MR. WOOL:

Q. Okay. And so that would include both your patients, anybody that would be referred to you, anything like

that?

A. That's correct. So that's different from exposures.

Q. Okay. Have you ever treated a patient with recurrent urinary tract infections?

A. I have several patients with urinary tract infections, that's part, being a part -- I would say 7 to 8 percent of my practice is recurrent urinary tract infections.

Q. Okay. And any of those that you attribute to mesh?

A. No.

MR. WALKER: Object.

BY MR. WOOL:

Q. Okay. Have you ever treated a patient with chronic pain that you attribute to mesh?

MR. WALKER: Object to form.

THE WITNESS: No. Can I elaborate a little bit on that?

BY MR. WOOL:

Q. Yes.

A. So when I say no, what I'm saying is I have treated patients with chronic pelvic pain. However, I do not think that it has anything to do with mesh.

Q. Were those patients treated with mesh?

MR. WALKER: Object to form.

THE WITNESS: Most of my patients have pelvic

pain because of vulvodynia, and that has got nothing to do with mesh, so even if -- so they do not have mesh.

BY MR. WOOL:

Q. So to be clear, you haven't seen a patient before that you treated for chronic pain, whether or not you attribute it to mesh, that also had been treated with mesh?

A. Could you repeat that again.

MR. WALKER: I think that misstates his testimony.

BY MR. WOOL:

Q. Okay. So let me try to clarify the question. So have you treated a patient for chronic pain -- strike that. Have any of your patients -- sorry. Have you treated a patient for chronic pain that you have also treated with with mesh for pelvic organ prolapse?

A. So if the question is that if a patient had pelvic organ prolapse surgery done with mesh, and she comes and she also has pelvic pain, oh, yes, I have several patients who have -- most of whether they had preceding -- and most of these patients have what we call bladder pain syndrome or vulvodynia, there are several patients who have this in common. I especially see this more with stress incontinence and bladder pain syndrome or pelvic

pain syndrome more than with prolapse.

Q. Okay. Have you ever reported a mesh complication to anybody?

MR. WALKER: Object to form.

THE WITNESS: Yes, if it is complication, if you mean by that is an untoward event like, for example, when I was doing the Exair study and I had the mesh exposure that happened in the vagina, I have to report it as an adverse event.

BY MR. WOOL:

Q. Okay. And you reported that as an MDR?

A. No, it was to the IRB, Institutional Review Board, the IRB.

Q. And, I'm sorry, that was in what study?

A. Exair. E-x-a-i-r.

Q. Any others besides that?

A. When I -- well, any study that I do, if there is anything which is -- which meets the criteria for adverse event, it has to be reported to the Institutional Review Board.

Q. Okay. So would you agree that pelvic organ prolapse is a functional disorder?

A. What do you mean by that?

Q. That it's not life-threatening.

A. No, I don't completely agree with that because I saw recently a patient who had a complete vaginal eversion and her ureters were part of that, and the ureters were kinked and she had significant hydronephrosis, so if this continued, her kidneys could fail, and that would become life-threatening. By the same token, there are patients with significant vaginal prolapse who could have urinary retention and they may not be emptying, and that could damage their bladder and cause perpetual bladder infections, so that could be life threatening. So I cannot really say that prolapse is not life-threatening.

Q. Okay. Would you characterize those types of cases that you just described as common?

MR. WALKER: Object to form.

THE WITNESS: Those which I just mentioned are less likely to happen.

BY MR. WOOL:

Q. Okay. So for most of the patients that you treat for a pelvic organ prolapse, is their prolapse life-threatening?

A. For most patients, no.

Q. For most patients, no. Would you describe pelvic organ prolapse as a serious condition?

MR. WALKER: Object to form.

THE WITNESS: I think that's something that we as physicians and across the table we can use, but it all depends upon what the woman thinks. For her it may be a serious condition, she cannot have intercourse with her husband because she doesn't want the vagina coming out, and for her this is life altering. You know, she would say I would like to have intercourse but I'm not having it because this thing is hanging out or every time I'm walking around I have to just find a corner to push this bulge in and it falls out again. So I don't think we can state that. I would say that the seriousness depends upon the patient's perception. If it is her perception that it is serious, well, then it is serious.

BY MR. WOOL:

Q. And so you said that it's based on the patient's perception, as I understand it?

A. That is correct.

Q. Okay. So that would be a condition impacting the quality of somebody's life?

A. That is right.

Q. That's the assessment you're making?

A. Predominantly.

Q. Okay. Predominantly. Okay. So on your website I believe you described prolapse as rarely serious. Is that your opinion today?
A. Yes.
Q. Okay. Now, how do you define success for prolapse repair?
A. It's, again, that is -- there are different ways of looking at it. What I believe in looking at a success is that you do something which the patient has a problem for, so you fix the problem, and you do not send her home with a new problem. That is success.
Q. Okay. So in your report you use a couple of metrics. You define success and some parts anatomically and some parts subjectively, objective, subjective, and composite; is that a fair assessment?
A. That is correct.
Q. Okay. So how do you define anatomic success or, sorry, let me just ask one more question. So when you say anatomic success, is that the same as objective success, those terms?
A. Let's see, well, objective success could be depending upon the parameter used, so if you're looking just exclusively from the point of your prolapse, only prolapse correction, then yes, but it could also mean

that objectively did she do better with her -- if we're talking about her incontinence, you know, or associated fecal incontinence, the associated symptoms, then it may not be just the prolapse, so then it may be different. But if you're looking from, example, the typical anatomic success would be based upon a POP-Q assessment, for example.

Q. So in your report when you refer to objective success, that is not just limited to anatomic success?

A. If it is the prolapse paper where I'm looking mainly for the vaginal bulge, then yes, if we're looking at objectively from the point of view of anatomic POP-Q.

Q. So, yes, objective success is equivalent to anatomic success in your paper?

A. From the prolapse standpoint.

Q. From the prolapse standpoint, okay.

MR. WALKER: And, David, you used paper, you used report. Could you maybe re-ask those to clarify what we're referring to because he does have literature that he's written.

BY MR. WOOL:

Q. Right. So in your published studies or any articles that you've written, the definition that you just gave me for objective success is the definition you use in

your studies?
A. That is correct.
Q. Okay. Now, is that an industry wide term, I guess would anybody, would any urogynecologist understand objective success as you described it?
MR. WALKER: Object to form.
THE WITNESS: It's -- no.
BY MR. WOOL:
Q. No? So in your expert report, I guess in some of the studies that you rely on, do you know if they define objective success the same way that you do?
A. Some did, some did not.
Q. Some did and some did not?
A. The difference, if you want to know, is that anatomic success typically has been defined as POP-Q stage 1 or better, that is the most dependent part of the vagina being -2 or better and -2 or higher, so that's the typical anatomic success. However, then Matt Barber from Cleveland Clinic, you know, they came up with a different definition of objective success which many people are now talking about, which is hymen, so does the vaginal bulge come up to the hymen. So now that changes. It's not stage 1 or stage 0, but even a Stage 2 could be okay if it comes to -- if it's just above the

hymen. In other words, the most dependent part before was -2. Now the most dependent part should be better than 0.

Q. So when you say before, what do you mean? Was there a time when this definition changed?

A. There is a time period of -- it's still, today even the POP-Q definition holds, so there could be papers published which show that the anatomic success as I initially defined stage 0 or stage 1, many people may say that is pertinent, this is what I'm going to base my paper on. So it has not dramatically shifted from one to the other, it is a gray zone of both these things. What happened is over the past few years physicians started thinking about quality of life, and from a quality of life standpoint they started thinking what does she want? Not what do I want. Objective success is what do I think, how does the vagina look, what does she think? So when we started thinking what does she think, there was a study that came from South Carolina which was done from Charleston, and they looked at women who came for a normal Pap smear, and what they found is that 65 percent of women who came for a normal Pap smear, they had no complaints of a vaginal bulge, they had the vaginas almost coming to the opening, they had a

Stage 2 vaginal prolapse, so most people would say that is considered a failure, you know, but again she was not complaining. So then when it started -- people started thinking when would she be saying that, hey, this failed for me, this is not good for me, would it be that high or would it be low. So that's when they started looking at the quality of life and what does the patient say. That's when the definition switched from stage 0 to stage 1, to prolapse at the hymenal ring or outside.

Q. When you say the definition changed, you mean the definition of objective success?

A. Correct.

Q. Okay.

A. So this is -- it includes subjective feeling that she says I have a bulge, but more likely women are going to say that I am bothered by the bulge, and this is a very good study from Denmark by Vierhout, V-i-e-r-h-o-u-t, from Denmark, and what they looked at was that when the vagina was coming to the opening, over 60 percent of women complained that they were having bothersome vaginal bulge, you know, that's why they said that let's switch objective success from stage 0 to stage 1 to anything that is just at the hymen or anything just above the hymen.

Q. Okay. Now, in your expert report you obviously cite a number of studies, and those studies, do they use a consistent definition of objective success?
A. No.
Q. No?
A. It's all over the place.
Q. Okay. And in describing the results using the term objective success in the study -- I'm sorry, strike that. So when you're describing the results of the studies in your expert report using the term objective success, does that definition change depending on the study?
A. It does.
Q. It does, okay. Now, how do you define subjective success?
A. So how do I define?
Q. How do you define and then I'll follow up.
A. So I define objective success -- subjective success as from the patient's standpoint, from prolapse standpoint we look at PFDI question number 3, which is from point of the view of the bulge, are you bothered by the bulge? And if she says no or slightly or rarely, then she is considered success. If she says somewhat or greater, she is considered failure from that question standpoint.

So most of our studies rely on that particular form. So what that allows us to do is it allows the patient to fill out a validated questionnaire, and we go by that validated questionnaire called the PFDI-20 to assess that rather than -- because if I ask someone, it's very vague, you know, how you ask. If I -- I could ask the patient and say you don't have a bulge, right? And she's more likely to say no. If I tell her do you have a bulge that's still coming out, she's more likely to say yes. So it all depends how the question was asked. So this again in literature has not being documented.

So the best way if you really want to know about subjective answers, it is important to look at validated questionnaires and then follow these validated questionnaires. So no words are put in patients' mouths, they look at the question, they circle it, and then we just tabulate at the end and see what they have.

Q. And are the questionnaires or the questions in the questionnaires measuring subjective success, are they uniform across most studies within the industry?

A. No.

Q. No? So the studies that you look at in your expert report, there are different definitions of subjective success?

A. Yes.
Q. Different criteria for each study?
A. Yes.
Q. So is there one sort of accepted definition of subjective success anywhere?
A. No.
Q. No? Okay. And you defined it in part as whether or not a woman is bothered by the bulge that she feels, so that would be whether or not in a way she is symptomatic, I guess?
A. From the bulge standpoint.
Q. Right, from the bulge standpoint. Do you see many patients who are not bothered by the bulge -- sorry, strike that. Let me see, do you treat many patients who have objective prolapse but not subjective symptoms?
MR. WALKER: Object to form.
THE WITNESS: A lot, a lot of patients come with that. I mean they would come in with something which is very, very important that you brought this up, because I have patients who can be sent by their gynecologist or their primary care physician, and they come in and they have a vaginal bulge, and it is obvious, they may have a stage 3 vaginal bulge where the vagina is coming outside. I ask them -- my first

question I always ask them based upon the PFDI is are you bothered by this, and she says no, then I show them the video, and I say this is your video, it's coming outside, are you bothered by this bulge? And she says no, I'm not bothered by it. That is most important thing for me. I say what are you bothered by? She said I go to the bathroom a lot, I've got urgency and frequency, and my doctor told me that maybe this bulge is causing your urgency and frequency. And I said let's wait. Let's figure out, it may be a bladder issue. Let's figure this out. And if it's not a bladder issue, then we'll eventually end up with this prolapse, but I see and what I do is I take care of that urgency or frequency or they may have like what you mentioned, chronic pelvic pain. Patient has a bulge, she comes with pain during intercourse, and bulge never causes pain during intercourse in most cases. So when I put -- when we take care of her pain usually with neuromodulation and the pain is gone, now she has the same bulge, it's still coming outside, stage 3 uterovaginal prolapse, and I ask them your pain is gone, are you able to have intercourse, are you bothered by the bulge? She says no. So I have a lot of women who have objective evidence of someone might say, oh, this

is a large bulge and should be fixed, but the patient has absolutely no symptoms.

BY MR. WOOL:

Q. Okay.

A. From the bulge standpoint.

Q. All right. Now, have you treated a patient that has no symptoms from that standpoint, from the bulge standpoint that objectively has prolapse?

A. Can you repeat that?

Q. I guess my question is have you treated a patient before that presents with no subjective symptoms with transvaginal mesh for prolapse?

A. No. I have treated them but not with mesh. So what happens is this. So let me -- I have to explain that to give you the answer. So let's say a patient has a vaginal bulge like what I described. Now she has urinary hesitancy, urgency, and frequency. However, on her voiding profile it seems that she's emptying well, so the bladder is coming out, intuitively you think, okay, the bladder is coming out, she's probably not emptying, that's why she has this urgency and frequency.

So what we do is we do some tests called urodynamics to assess whether the bladder is working well or not. Then I would do what is known as a pessary

therapeutic trial, so I put a pessary inside, reduce the bulge, push it back inside, and then see what she says. She may come back and say, oh, my God, that made a big difference, now I can empty better, my urgency and frequency has improved, this is great.

Then so we can say, okay, what the pessary did is it simulated a surgical repair, that's what surgery would do. So now correcting the vaginal bulge in someone like you who initially was not complaining of a bulge but has associated symptoms which were managed by reducing the bulge, in such a patient definitive treatment of prolapse would be recommended. So at this stage I would approach her and say, okay, you have noticed that your urgency and frequency have improved with the pessary. You could either continue with the pessary or we can go and take care of and repair this. And then she says yes, I had noticed the bulge, I had noticed the bulge, and since my symptoms have improved I would want to go ahead with this. That's one example.

Another example of what you said, no subjective symptoms, patient comes in and tells me I have this, I don't know, I didn't know this was a bulge, I'm not bothered by it. When we educate them, when I show them the video and say this is what is coming out,

this is what is happening, there's no damage, she's not one of those life-threatening patients I mentioned, she is doing fine, she is overall emptying her bladder well, she just has the bulge. However, once you make them aware that this is what it is, this is the bulge, this is where it should be, this is where your anatomy is, so then she says, oh, I didn't realize it was coming out that much, that's significant, let me go home and think about it. Now she starts understanding what is happening, and then she may say, yes, I want this fixed.

The third scenario is where a patient similarly says I'm not bothered by this. Why? Because she has heard, read all these vaginal mesh ads on TV, so she says forget it, I do not want surgery. Once she comes in, she hears evidence-based information from us, the real balanced information, risks, benefits. Now she says yes, I was bothered by this, I was so concerned about what's out there on TV ads so I did not want to even get into this, but now that you've explained to me in a proper manner, I want this taken care of.

So these are a few examples where a patient may not have subjective symptoms, has objective findings but actually does have some subjective symptoms linked to the objective findings; however, I did not treat just

the objective findings, I treated the subjective findings after counseling the patient and making her aware as to what she was experiencing.

Q. Okay. Now, in your own practice, how do you define success, one, objective, subjective, a combination of both?

A. So what we want, what we strongly believe is that I want -- like my composite score is I want to do something for her that she's come with, she came with a problem, I want to fix this problem, but I do not want to give her another problem. That's what we consider success.

Q. Not giving a patient another problem?

A. Correct.

Q. So if a patient doesn't present for another surgery or another treatment, that would be success?

A. No. If she came in with prolapse and I fix the prolapse and then she said that I did not have, you know, incontinence before, now I'm having incontinence, so she didn't have it before, now she's having it, so that means the surgery led to another problem. So we want to make sure that if we can therefore cover the whole thing, which is typically not reported, it's -- if you look at this composite score and look at anatomic score,

the anatomic score percentages will be 95 percent. To the eye it looks perfect, but to her it may not be perfect. So what matters to our practice and to me as a physician and a proponent of women's health is that I don't want to do anything that she did not come with. I hope I do no harm, that's my oath. So I want to do what I can do and I don't want to do any harm, so that's my success. So it's very -- it's -- I can't pin it to one thing, it's a general term, but basically factor about take care of the problem she came with, don't give her any new problems.

Q. So a combination of objective success, subjective success, and no new problems, is that a fair characterization?

A. That's correct.

Q. Okay. Now, in your own studies you typically use a composite score of success?

A. Yes, and, however, in the discussions usually to break it down to compare apples to apples, let's say if a paper has been published by Joe Shmoe and they discuss anatomic success only, so say our anatomic success was this and this is what they showed, because if you look at papers, a classic example I would give you is a paper that I was involved with, it's part of the Urinary

Incontinence Treatment Network, UITN, and it was a Tomus, T-o-m-u-s, and S-i-s-t-r study. In that, we mention absolute definition of cure, that on the MESA, M-E-S-A, which is an incontinence validated form, the patient has to say never, I have no problems, zero. So if she says no, no, no, then she's considered a success. Our success score with a sling, which is the fascial sling, was 50, 55 percent. The typically quoted success out there is 95 percent success. So how come ours was 55 percent for fascial sling where theirs was 95 percent? Because it's the definition of success. It was a very hard defined definition where she had to be absolutely a no. So if you look at our paper, at this 55 percent, and someone else says these people are bad, but, no, the definition is wrong. Now, when we compare to what they define success as, which is an objective leak test, so she coughed and leaked, our success was very similar to theirs, when you look at that parameter that they went by, but not the strict parameter that was used in this study.

Q. So your definition of composite success in your studies, how is that measured, I guess? Is it a 50/50 split of objective and subjective or just tell me what the definition is.

A. That's a very good point. So we look at everything, absolute, she has to meet all those criteria. For example, if I looked at, for example, the incontinence study I'm doing right now, it's very fresh in my mind, I'm doing a single incision sling right now, so that I would look at is she dry, number one. Number 2, does she have any de novo urgency, so the definition would be patient is subjectively dry, so on the MESA form she said I'm not leaking or, Number 2, objectively she's not coughing and leaking, so that's what she came for, her incontinence, that's one part. Did I give her anything bad? Does she complain? So then she should have no voiding dysfunction, she should be able to urinate fine, no catheter, no de novo dyspareunia, no de novo urgency incontinence, no mesh exposure, no de novo pelvic pain. So these are the bad things that could happen when I put a single incision sling. And so I think -- they have to answer no, no, no, no. So if they meet all that, then they consider it success.

Q. Okay. And in your studies that you cite in your expert report, in all of them, I believe, the objective success rate is higher than your composite success rate?

A. Yes.

Q. Okay. And you would agree that the composite success is

more important to you as a physician?

MR. WALKER: Object to form.

THE WITNESS: Absolutely.

BY MR. WOOL:

Q. Okay. Let's see, so of your own studies that you cite, which are specific to the Prolift?

MR. WALKER: And, Doctor, feel free to reference your report.

THE WITNESS: Yes.

MR. WALKER: If that will help you.

BY MR. WOOL:

Q. I think you cite some 60 studies.

A. I think he's asking me about my studies.

Q. Yes.

A. It's the first one, the 315 patients.

Q. Okay. Have you ever been involved in a clinical trial comparing a midurethral sling to another pelvic surgery?

A. Like what? Pelvic surgery you mean?

Q. Being either a native tissue repair, any -- not -- any surgeries that don't involve mesh.

A. Yes, and that was the -- it's a Burch, it was the UITN study which is Burch versus the TVT.

Q. Now, are you currently working on any studies or writing any articles?

A. On what? Generally?
Q. Generally, yes.
A. Yes, we have about eight open clinical trials right now.
Q. And what do those involve?
A. One is -- most of them involve urinary incontinence studies and vaginal prolapse studies. So one is on the Exair mesh, the other is on Elevate vaginal mesh, third is on Miniarc sling, M-i-n-i-a-r-c, and the different derivatives of that, and I'm looking at an overall vaginal mesh outcome paper.
Q. Are any of those studies sponsored by an industry group?
A. The Exair was, it was at my -- it was -- that's a different thing, it's not sponsored by the definition that they made me do it, it's something called investigator initiated study. So I've made the proposal, I send it to their research division, and they get a lot of clinical trial requests, and they pick and choose and they say, okay, yours is a good trial, we would like to do that. So I have that for Exair. It's a vaginal mesh Exair study.
Q. But they financed part of the study?
A. They financed it, yeah.
Q. Okay. Have you ever published anything on the porosity of mesh?

A. No.
Q. Any publications on degradation of mesh?
A. No.
Q. Have you ever published on the shrinkage of mesh?
A. I don't understand these terms, though, but no.
Q. Have you ever published a study on mesh contracting or changing shape once it's implanted?
A. I don't even believe in that.
Q. So you haven't -- have you studied whether or not mesh contracts yourself?
A. Yes.
Q. Okay.
A. In my paper that I published, we looked at what is called a total vaginal length, and we assessed it before the procedure and after the procedure and concluded there was no difference in the length. It's similar to the paper by Dietz, you know, who -- and from Canada, what they did is they did an ultrasound study, and they found that there was no contraction of the mesh at the ultrasound.
Q. Now, what was the follow-up time in your study?
A. Let's see here -- look at my Prolift+M -- so this was a 2008 to November 2010 composite score, so these are patients followed up at least a year out, at least one

year out the patients are followed up.
Q. And that was with the Prolift?
A. Prolift+M.
Q. Prolift+M. Any studies on shrinkage of mesh that involve the Prolift?
A. I don't believe in shrinkage of mesh.
Q. Or any clinical results that would either confirm or support the lack of shrinkage of mesh with the Prolift?
MR. WALKER: Object to form.
THE WITNESS: Can you repeat the question.
BY MR. WOOL:
Q. Sorry. Have you ever conducted any studies dealing with the Prolift where you measured the length of the vagina following the surgery to look for contraction of mesh?
A. Well, I did my clinical trial to see for outcomes like what I mentioned, so my main focus is to see what patient outcomes are and how she is doing and what are the results. As part of that, we looked at the vaginal length, and we compared the vaginal length before and after, and there was no change.
Q. Now, in the Dietz study that you referenced, did that study use Gynemesh or any mesh manufactured by Ethicon?
A. I would have to look at what they used, but what they did find was there was no shrinkage in the mesh, but I

don't remember if it was Prolift or Prolift+M.

Q. And you said you don't believe in shrinkage of mesh?

A. That is correct.

Q. And what's the basis for that opinion?

A. Because, if anything -- I mean there are several research papers that I have reviewed which basically show that if there is anything -- let me put it this way. So what happens is that once the mesh is put in, and we've seen this in normal prolapse management even with the pessary, when the vagina is falling out, typically the vaginal walls stretch, so it looks much larger. As the prolapse is reduced, for example, even when you put a pessary inside to reduce the bulge, over time the vagina is being a live tissue, it starts narrowing, it starts accommodating within itself because now it starts getting -- it starts shrinking, in other words, the vaginal walls itself. So the pessary that we use also goes down in size. So many a times we have to change it, if it is like a number 7 pessary, we'll go down to a number 6 pessary, because now the vagina has accommodated within its place where it was, because now it's not stretching and getting distended by the bulge. Similarly, in surgery what we do is we do not cut the vagina, we basically open the vagina, that's the beauty

of vaginal mesh augmentation surgery, you open the vagina, you put the mesh in, you therefore support the underlying organ, whether it's the bladder or enterocele or the uterus or the bowel. Once you support all that, then you close the vagina.

Now, before you close you can see that the vagina has already elevated -- the subvaginal area, the bladder is already elevated and it is held up by this augmented mesh. Now, the vagina eventually goes and conforms to that. So there is no shrinkage of the mesh, it's the surrounding tissue that accommodates to that mesh, the mesh being as it is. So then it is an apparent perception that the mesh and the whole thing is shrinking, but it is just accommodating to where the mesh has been placed.

Q. Okay. And have you ever conducted any ultrasound studies yourself?

A. No.

Q. No? Okay. So any studies you rely on besides the Dietz study to support this opinion?

A. Yes. There's a study, I think it was, if I'm not mistaken, it's Elmer, you know, the Nordic group, Elmer, they basically, what they showed is that the total vaginal length did not change during -- but they didn't

do an ultrasound study but did the vaginal length assessment study, and they did not see that there was a change in that. But of course my experience is very robust because I have done it with several -- I mean I'm quoting 250 patients I saw before and after.

Q. And all those patients are your patients, correct?

A. Yes.

Q. Any background in polymer science?

A. Myself? So if I have any training in polymer science, no.

Q. Are you a biomaterials expert?

A. No.

Q. No. Have you conducted any bench research on --

A. No.

MR. WALKER: Let him finish the question.

THE WITNESS: Bench research on --

BY MR. WOOL:

Q. On either Gynemesh in the Prolift or the mesh in the Prolift+M?

A. No.

Q. No? Have you ever evaluated mesh explants?

MR. WALKER: Object to form.

THE WITNESS: Could you explain what you --

BY MR. WOOL:

Q. Have you ever conducted a microscopic evaluation of explanted mesh?

A. No.

Q. No? Are you an expert in biofilm?

A. No.

Q. Are you a pathologist?

A. No.

Q. Polymer chemist?

A. No.

Q. Okay. And you're not a --

A. I'm not a pathologist by definition, but I do look at slides.

Q. And you're not a toxicologist?

A. No.

Q. And not a radiologist?

A. I do look at ultrasound, but I'm not a radiologist as a professional, so if I do an ultrasound I would look at it, we do anal rectal ultrasounds all the time in my office. So that's a very general term, but as a degree, I'm not a radiologist, but I do ultrasounds on my own.

Q. But no ultrasounds on your own studying mesh after it's been implanted?

A. No.

Q. Okay.
A. If there's a trial I proposed, but we haven't got the funding yet.
Q. Okay. Have you ever seen a pathological analysis of explanted mesh?
A. In what -- can you describe it? What do you mean by that?
Q. I guess just an analysis conducted by a pathologist of mesh that has been explanted from a patient.
A. It just -- in I think in literature --
MR. WALKER: Are you talking about a clinical study surveying multiple patients or just a single pathology report?
MR. WOOL: Right, either/or, I guess. Let's start with a single pathology report.
THE WITNESS: Pathology report, I am not sure, but I may have reviewed in one of these cases, I believe a report by a pathologist, Dr. Yacoff (sic) or something.
BY MR. WOOL:
Q. Now, any studies that you've reviewed -- any studies that you've reviewed of pathological analysis of explanted mesh?
A. Yes.

Q. Okay. And what studies were those?
A. It's a study by Clave from France, C-l-a-v-e.
Q. And is that the only study?
A. From -- and let's see, no, I can't recall the names, but I can -- I have the information, but I can't recall the exact names of the authors.
Q. Okay. So have you ever performed a study of polypropylene mesh and its effects on a woman's body?
MR. WALKER: Object to form.
THE WITNESS: Could you please repeat.
BY MR. WOOL:
Q. Have you ever performed your own clinical study of polypropylene mesh's effects once implanted?
A. Yes.
MR. WALKER: Same objection.
BY MR. WOOL:
Q. Okay. And what study was that?
A. All these studies, these are the effects of polypropylene mesh on the vagina, how the anatomy is corrected.
Q. Any of the studies deal with inflammatory response to the implanted mesh?
A. What do you --
Q. Did you ever study the inflammatory response of the body

to implanted mesh?

A. I don't think that exists. So I would not be studying something I don't believe exists.

Q. All right. Okay. So moving on, okay, now, are you offering a general opinion on the appropriate use of Ethicon mesh for stress urinary incontinence patients in this litigation?

A. I think it's more for the vaginal prolapse, I mean I could but it's more for vaginal prolapse.

MR. WALKER: Dr. Khandwala has only issued general reports for Prolift and Prolift+M.

MR. WOOL: Okay. I just wanted to clarify.

THE WITNESS: Yes.

BY MR. WOOL:

Q. Okay. And --

MR. WALKER: In Wave 1.

MR. WOOL: Right, just this, just Wave 1, okay.

Do you consider yourself an expert in polypropylene?

MR. WALKER: Object to form.

THE WITNESS: What do you mean by that?

BY MR. WOOL:

Q. I think the question's sort of self-evident, but on the

properties of polypropylene, do you consider yourself an expert on --

MR. WALKER: I mean are you talking about its use in vivo? Are you talking about from a biomaterials standpoint?

MR. WOOL: From a biomaterials standpoint.

THE WITNESS: I have a lot of knowledge about the mesh and the material because I have used it extensively since -- decades now polypropylene.

BY MR. WOOL:

Q. So --

A. So clinical information, I have theoretical information, because that's when I mentioned about why did I go from Prolift to Prolift+M and how the mesh changed, you know, what was the addition of Monocryl, so I was very much interested in knowing what this thing was, so from that standpoint, yes, I do have.

Q. So you would consider yourself an expert?

A. Well, I don't know what that means, but from --

MR. WALKER: Object to form.

THE WITNESS: -- overall from the knowledge basis and I think it's a very subjective term, expert.

BY MR. WOOL:

Q. Have you ever studied the effects of, I guess, human

tissue on polypropylene, not looking at, say, the patient but looking at the polypropylene mesh after it's been implanted?

A. Well, I always follow my patients, and I've been doing this -- they usually come in at the 2-week visit, the 6-week visit, three months, six months, 12 months, and we try to get them at their 24-month visit. So this is the best way to see a patient, this is in vivo. So I'm examining these patients, I can feel how it looks, I can see the vagina, I can feel at the same time I hear the story. So that's the best study you can ever do is in vivo. Nobody can do a better study than a physician examining a patient who has been implanted by a polypropylene mesh over a period of time.

Q. And so in that instance, you're examining the patient and the vagina, correct?

A. Correct, and asking her symptoms and her history.

Q. But you're not particularly looking at the polypropylene itself, are you?

A. In a way I am, right, because if the polypropylene is implanted in her, you know, if something is going on, I would know that. If it's good, that means if it's perfect, that's what we want. So if there is no complaint from the patient, there is nothing bad

happening, and we are following this up, I mean who better could know the effect of polypropylene in the vagina than the physician who is following this patient over time, because you're looking at it, you know what you're looking at. If there's something that is happening, you would obviously be able to identify it.

Q. But what you're not looking at, I guess, and this is my question is you're not looking at the effect of the vagina on polypropylene, are you?

MR. WALKER: Object to form.

THE WITNESS: I'm looking at the interaction, it's an interaction, the vagina on the polypropylene, the polypropylene on the vagina, so it's the interaction, because as you examine the patient, you see the interaction of this whole thing. So I don't think we can differentiate. I think the best way to look at it is how does she feel? How does she feel herself with this thing in, and how do I feel on exam. So it's a combination. So on exam what I basically described, you know, what you mentioned is the total vaginal length. From the history, what she is saying is how does she feel, and she says I can have intercourse, I am very happy, you changed my life, I do not have any other problems. Well, that's all that matters. That's really

all that matters. That's exactly why we're using this mesh in human bodies, is because all that matters is are we changing this person's quality of life, and that's what I am about.

Q. Okay. So I guess given that you're looking at the quality of life of the patient, would it matter if mesh degraded a bit?

MR. WALKER: Object to form.

BY MR. WOOL:

Q. As long as the quality of life is sufficient?

MR. WALKER: Object to form.

THE WITNESS: I have done this vaginal mesh reconstruction for over a decade, and I've done it in over a thousand cases, I probably have 1,500 cases where I've implanted polypropylene. I've never seen this happen.

BY MR. WOOL:

Q. Okay. And you're offering a general opinion on the use of polypropylene mesh?

A. In prolapse.

Q. In prolapse, yes. Okay. So let's take a look at your general report, and I know you have a copy of that. I've got one. Let's mark this as Exhibit 5.

KHANDWALA DEPOSITION EXHIBIT NUMBER 5,
DEFENSE EXPERT GENERAL REPORT OF
SALIL KHANDWALA, M.D.
WAS MARKED BY THE REPORTER
FOR IDENTIFICATION

BY MR. WOOL:

Q. And if you look at Page 7, it looks like you're saying that that mesh provides a high first-time success rate and an attractive safety profile?

A. Which paragraph are you reading?

Q. It looks like the second to the last paragraph.

A. Yes.

Q. Okay. So how do you define safety profile?

A. So that there are two things, operation combining higher rates of first-time success with an attractive safety profile.

Q. So just the safety.

A. Safety is where there is no problem or complications that I would see or my patient would encounter on the safety standpoint. So now there are different aspects. What I'm talking about is the surgery. So I'm not -- this is -- so it's important to define what is being discussed. We're talking about vaginal mesh surgery, so it's an entire procedure, not just about placement of a

particular material, you know. So how does that whole surgical experience impact her overall outcome from the point of view of any untoward outcomes? That's safety. So she should not have any untoward outcome such as the bleeding, infection, injury to the neighboring organs, and all those things, and then any functional outcomes afterwards, reoccurrence of prolapse, de novo incontinence, whether it's urinary or bowel, de novo pelvic pain, de novo pain during intercourse, so all those things are involved when we discuss safety.

Q. So you're looking at safety both in the surgical process itself and the results following?

A. Correct.

Q. Okay. And what's the basis for the opinion on the safety profile of mesh in pelvic organ prolapse surgery?

A. My experience.

Q. Your experience?

A. By that time I've done so many cases, and clearly it was very evident when I switched, as I had mentioned initially my frustration with vaginal native tissue repair with these large prolapses, because literally I realized at that time what am I doing? You know, I'm taking this uterus out and I'm putting nothing to nothing, it's all attenuated stuff, and every physician

would then tell their patients come back in a few years and it could last for a few years and it'll be back. Well, I don't want that. I wanted something that could be as permanent as possible, and what is the best shot I can give this patient. So when you're especially looking at that word what I mentioned large prolapses, which typically what I was discussing, stage 3, stage 4 prolapses is where this has a higher success, and at the same time the safety has a lot of factors, it depends upon the surgical technique, you know, how do you dissect the patient's anatomy, what she presents, does she have recurrence, does she have scar tissue, there are so many factors involved.

Q. So I guess is this opinion on the safety profile, is that limited to prolapses of stage 3 or greater?

A. No. Any surgical intervention that's done for prolapse where I use in this case vaginal augmentation surgery, that's what I've alluded to.

Q. Okay. So are you offering an opinion for the safety and efficacy of the Prolift or the Prolift+M for posterior surgery?

A. Yes.

Q. And what's that opinion?

A. Well, many factors. Number one is my own personal

experience. I can tell you the main reason why I do a posterior vaginal mesh reconstruction -- for two reasons. One is when I go in and when I open up the vagina and I find that the tissue is completely attenuated, which is the tissue between the vagina and the rectum, then I would interpose a mesh, because, again, my goal is -- my main goal is I want to do the best I can for this patient at one time. I do not want this lady to come back again, that's number one.

Number two -- so attenuation of tissue is one. Second is the best apical lift that you can give is through a posterior mesh. So it's not just to repair the rectocele but mainly to support the apex, and that is the crux, what we -- most urogynecologists now believe the crux and management of vaginal prolapse is supporting the apex. The best way to support the apex is posteriorly. Anteriorly can be attempted. However, posteriorly is much better. That's the second.

The third thing is that if a patient essentially comes with a front wall prolapse and someone just does an anterior vaginal wall repair with mesh and they don't do a back wall repair, the problem is that there is a high risk of recurrence of the contralateral wall, and this has been shown in numerous studies,

especially the study from Amsterdam by Withagen, W-i-t-h-a-g-e-n. And they have shown that when you repair one wall, the contralateral wall can fail at a higher extent.

And so what I am is I am like an engineer of the vagina, for example. So let's say if you have this wall in this room. One wall has an obviously crack, and you get someone to repair it, you know, say, okay, fix this wall, but that engineer is now going to focus on what you've already seen. It's obvious -- if it's obvious to me as a lay person, it is obvious to the engineer. What they will focus on is how is the contralateral wall, is this wall sturdy enough or not, and they can do some tests and find out that this wall also is weak.

So when I examine a patient, the obvious wall could be the anterior wall falling down. However, there may be what is called as an obvious bulge but may be occult, may not be that obvious initially, because when the patient strains, the entire pressure goes along the front wall, so now the front wall is being subjected to the prolapse, but the back wall appears to be okay, but it may not actually be. So in a proper assessment it may look it's just as anterior wall prolapse, but it's

also an occult break at the posterior wall. So these are the different reasons, plus the paper that is published by Withagen I just quoted showed a 24 percent risk of recurrence after a nonmesh as opposed to 4 percent with mesh for the posterior vaginal wall.

Q. So I guess to clarify it, are you saying that mesh is safe and effective for treatment of posterior prolapse?

A. Mesh is safe and effective when the indication is correct, just the indication I stated.

Q. So when those indications are present, it's safe and effective for posterior prolapse?

A. Absolutely. I can even tell you that there is a Cochrane review done by Chris Maher from Australia, M-a-h-e-r, and what he showed is that when they compared the mesh to nonmesh repairs, they said that in -- for posterior wall, it doesn't matter, mesh may not have an advantage, so that's very subjective. It depends upon every individual patient. So you can't generalize. Cochrane reviews are guidelines. See, most people, whenever statements are made, they are guidelines, they are guidelines that tell the physician, hey, this could be the way that you should be leaning towards or this is what is taught, suggested, but every patient is different. So if I go into a person and open up the

back wall of the vagina with the plan of, you know, she has a stage 2 rectocele, I'm just going to put the tissues together and do a native tissue repair, but when I go in and I open up the vagina and I find nothing, I said this -- in my experience, from what I am seeing here, there is nothing I can put together. I need to do something better for her. And that's when I would augment it. So it's very tailored, it's very individualized.

Q. Okay. So on Page 10, the last paragraph, you say that mesh augmentation has typically not been shown to be of added benefit to colporrhaphy.

A. That's the paper I quoted by Chris Maher, so that's the one I was talking about. So when Chris, when he showed this study and the meta-analysis, and looked at different studies, that posterior vaginal wall, mesh may not bring any benefit, but that again depends upon what it is. And the other paper I talked to you about was the Withagen paper and the paper by Myles Murphy, which is the FDA update or FDA rebuttal. In that FDA rebuttal, Myles Murphy clearly, in the paper that we wrote, it clearly shows that it has some effect. At the same time it's mainly indicated, it's mainly indicated for the apex. So when I'm supporting the apex, that is

key, and that is why a posterior approach is important, because it supports the apex. It's not necessarily to just correct a rectocele.

Q. Okay. So I guess given that opinion, I guess, can you sort of help me understand the reason for including the Maher study where I guess you say that they report no definitive conclusions about using mesh for posterior repair?

MR. WALKER: Where are you --

MR. WOOL: Sorry, the top of Page 11, first paragraph Page 11.

THE WITNESS: Yeah, so that's the Cochrane review I was mentioning. So I just want to be broad. I want to make sure that people when they read this report understand that there are two sides of the same thing, you know. You have -- there are reasons why it may not be, there are reasons why it may be. So ask me why would I use it? So do I always use a mesh in the posterior compartment? No. Just like what I mentioned. If the tissue is intact when I open it up, I put the tissue together, because, yes, posteriorly it's not that much of a problem. We do not see that much of recurrence. However, when you open it up and there is no tissue there, then you have -- and you should augment

it, so there is no way to know going in if you have a -- most rectoceles could be Stage 2, so when you're going in, there is no way to know that am I not really going to put a mesh? Am I going to put a mesh? You never know what to expect until you open the vagina, and then you identify what is below that. And the second thing what I mentioned is for the apex. So what I've realized, especially we are one of the leaders in doing this vaginal mesh hysteropexy, so when we do the mesh hysteropexy procedures, if you are doing the uterine support, you have to have an anchor to the back wall of the uterus going to the sacrospinous ligament, and that is what the posterior mesh allows us to do. So the importance is not just for the rectocele. What he's talking about is overall just looking at a rectocele, but I'm talking about that that's why I put it in there. So, yes, for majority of reasons it may not be required, but for a lot of other reasons, especially now where the focus is shifting on the 2011, now it's shifting to the apex, we are now understanding that apex support is very important, especially when it comes to preserving the uterus, and that's what we have been doing, and that's the paper -- and that's where the posterior mesh is extremely important to hold it up.

BY MR. WOOL:
Q. So I guess is your opinion that in certain cases use of mesh in the posterior compartment is beneficial?
A. Yes.
Q. Okay.
MR. WALKER: David, I don't want to break your flow up, but by my count, we're at two hours, and perhaps we could take a break.
MR. WOOL: Yeah, that's fine with me. We can go off the record.
(A recess was taken from 11:21 a.m. to 11:30 a.m.)
BY MR. WOOL:
Q. Are you offering a general opinion on the reactiveness of polypropylene mesh for the Prolift?
A. Could you repeat, please?
Q. Are you offering a general opinion on the reactiveness of polypropylene mesh for the Prolift?
A. What do you mean by reactiveness?
Q. Does the mesh react with the tissue once implanted and either change shape or form for the Prolift?
A. See, what I look at, as I've mentioned, is that my opinions are based upon what has happened over time when I'm implanted this mesh, and I contend that ever since I

started implanting the mesh I have never had any issues which -- what you mentioned like a reactiveness, I've never had --

MR. WALKER: Just to clarify, like I stated at the beginning of the deposition, he is prepared to offer opinions on the biocompatibility of the mesh in both devices.

BY MR. WOOL:

Q. Right, I guess to clarify, what I would say is it's my understanding that you would say that the Prolift+M does have some reactiveness and that -- what's the chemical that I can never remember --

MR. WALKER: The Monocryl?

BY MR. WOOL:

Q. Yeah, Monocryl dissipates over time.

A. Yes.

Q. So with the Prolift, I guess, no part of -- it's your opinion that no part of the mesh dissipates or disintegrates, changes over time?

A. That is correct.

Q. Okay. And with the Prolift, it's your opinion that the Monocryl dissipates over time?

MR. WALKER: Object to form. I think you misstated that.

THE WITNESS: Prolift+M.

BY MR. WOOL:

Q. Yes, sorry, sorry. The question should be and it's your opinion for the Prolift+M that the Monocryl dissipates over time?

A. Correct.

Q. Okay. Now, shifting back to the Prolift, what is the basis for your opinion that the mesh is not reactive?

A. My clinical experience, you know, I have -- I can tell it from different ways. One is just following patients over time, which is the main basis, what patients are doing, how do they feel, how do they -- and on exam and different ways of examination, dynamic, which is during intercourse, how do they perceive that, and during my physical examination during follow-ups, that's the main basis.

Q. Okay.

A. Second --

MR. WALKER: Go ahead, continue.

THE WITNESS: I'm sorry, what exactly are you asking?

BY MR. WOOL:

Q. Can you read the question back?

A. I think I got it. The second part I think you mentioned

is that is there any concern, and even when I have seen patients, what I mentioned about with proper placement, it looks as though the vagina has been reverted to normal anatomy, that's what it is.

Q. Okay. And the study that you looked at, I believe the Dietz study that formed part of the basis for your opinions on shrinkage and contraction of mesh, did that study focus on Ethicon mesh specifically or do you --

A. You know, that, I don't recall whether it was -- which type of mesh -- what it was focused on. I can review it quickly and tell you.

Q. Sure.

A. Sure.

MR. WALKER: Do we have that in the stack? We can look for it during a break.

BY MR. WOOL:

Q. Okay. And you state in your report that the FDA's opinion on contracture is not supported by data, correct? I believe it's about Page 16 of your report.

MR. WALKER: Are you talking about the bottom paragraph?

MR. WOOL: Yes, the last paragraph on Page 16.

THE WITNESS: Yes. I'm sorry, can you please repeat the question.

BY MR. WOOL:

Q. It was, I believe it was whether or not it's your opinion that the FDA's opinion on contracture was not supported by data?

A. That is correct.

Q. Okay. And what is the basis for your opinion on that?

A. Well, it's my own personal experience that I have never seen a mesh contraction, even in -- even in examples I can give you is when there is exposure which I have managed expectantly over a long period of time, so exposure I define as when the vaginal mesh is seen in the vagina, where the epithelium is separated and you can see the mesh, in all those cases, also, when we follow these patients up it does not change at all, even though the mesh is exposed to the vagina which has its own bacterial flora, it still does not change form, it remains as is.

Going further, when I have removed in a few cases those exposed mesh pieces, they were strong as though I had just put in yesterday, so nothing has happened to this. Despite the fact that it has been exposed to the vaginal flora, nothing changes. So there is no contraction, nothing happens. So my clinical experience clearly shows that this does not happen, and

it has been supported in literature, also.

Q. So when you follow up with patients, what is the time frame that you're typically looking at?

A. So we see our patients back in two weeks, then in between four to six weeks, then three months, six months, 12 months, and then try to get them at 24 months.

Q. Okay.

A. And then 36 months if feasible or if part of a clinical study.

Q. Okay. And at all of these junctures you are measuring contraction by looking at the vagina itself?

A. So we -- at every visit we do a few things. First of all, we give the patients validated questionnaires, and then we compare the validated questionnaires to the ones before, so these are just tabulated, and these include the ones I mentioned, the PFDI-20, which goes over the prolapse questions. Then we examine the patient and do a POP-Q assessment on every patient who comes in for subsequent visits, and we note that, which includes the total vaginal length, and that is how we compared in that paper whether there was a change in vaginal length from before to after based upon that evaluation, and we also do the palpation of the vagina.

Q. Okay. So I guess would you agree that contraction or shrinkage of mesh would be an objective type of measurement?

A. Well, first of all, I don't think that, as I've mentioned before, I don't think the mesh shrinks, that doesn't happen. So if it doesn't happen, there is no way to measure it. I've always maintained and I've always seen that it is the vagina which conforms back to normal anatomy, and because it conforms back to normal anatomy it appears that it's shrinking, but it's actually just -- it's a live -- vagina is live tissue, and it's going back to where it was placed. Think about this. You have this vagina which is falling out, so it's all distended and separated because it's falling, so it's distending. Now you put it back inside, it's no longer distending, nobody's putting stretch on it, so now it being a live tissue, it's now reorganizing itself and it conforms to its normal surroundings. You know, that's why it appears as though there is shrinkage, but actually it's returning back to what it was normally there before prolapse happened. Prolapse led to -- so I would actually say opposite, I would say that prolapse led to the vagina getting distended and opened up wide, that's why it's coming out, so the more it bulges, the

more it stretches. Once you put it back, you are actually returning it to normal. So what some people may say is shrinkage, what I'm saying it's returning to normal vagina.

Q. Okay. And could a patient questionnaire give you an objective measure of mesh shrinkage, imagine for a minute that this was something that you believed in?

A. Well, first of all, I don't believe it, so I can't say that. But if the patient -- the typical thing let's say if there was any operation done in the vagina is associated with some scar tissue formation, it has to happen. Scar tissue essentially is a -- essentially whenever you put a foreign body, there are seven things that happen: First is there's injury because you're dissecting that space. Second is something called protein absorption, so there's bleeding, and from the blood vessels there's protein that comes out, and that protein attaches and called protein absorption. Third, there is acute inflammation, which is release of something called neutrophils. Once acute inflammation settles, then there is something called chronic inflammation where there's monocytes or macrophages that come in, that's the fourth step, macrophages that coalesce to form what is known as giant cells of multi-

nucleated macrophages or giant cells. This is called a foreign body reaction, which is the fifth step. The sixth step is granulation tissue formation, which is fibroblast and vascularity comes into that space, so there's neovascularization with fibroblasts, and the seventh step is encapsulation. This happens no matter where you do it. I do a lot of interstim procedures, which is placement of a pacemaker, the battery, in the buttocks, and that's for overactive bladder control, for example. So when I go in, suppose I have to replace the battery because the battery's expired, not working, when you open up, you can see this encapsulation. It happens with a cardiac pacemaker, it can happen with this pacemaker, it happens with hip prosthesis, it can happen with any foreign body, there is this classic something called foreign body reaction, it happens.

Q. Okay. So, for example, an ultrasound study like the Dietz study, would that give you an objective measure that the mesh is not contracted?

A. It would look at the mesh and say how it was placed. The big difference is it has to be done before and after. So if they did it before and they saw how the mesh was and afterwards and you see how the mesh is, all it can tell you is that was that -- did the mesh itself,

how was it laid? And in that study, what they found that there was no shrinkage of the mesh itself. It was more of the tissues around it rather than mesh itself, you know, which was the problem.

Q. So that you're saying definitively tells you that there was no mesh shrinkage?

A. That's correct.

Q. Okay. And so could a patient questionnaire ever give you a definitive answer, objective answer on something like that?

A. A subjective answer, yes, because it will give you a subjective answer, a questionnaire. So it'll tell you what she's thinking. So a classic thing is if there is any contraction or scarring, you know, or shrinkage of the vagina or the vaginal epithelium, her main thing is going to be pain, discomfort during intercourse because of loss of elasticity. And that is more likely to happen in native tissue repair than with mesh as has been shown by several papers, Niemenen's paper, N-i-e-m-e-n-e-n, or Noonan and Brunett when they published the paper, they showed that patients had pelvic pain which is more resolved after mesh and more pelvic pain persistent after native tissue repair. So this is an element of operation in the vagina and what

is done. So scar tissue formation decreases elasticity, because when fibroblasts form, you have scar tissue, so elasticity goes away, and when the elasticity goes away, you do not have that distensibility that normally happens at foreplay, for example. So what the patient will tell you is I have pain during intercourse. You know, that is the only thing that she could tell that I have possible scarring.

Q. And I'm sorry to interrupt you, I don't think that you're answering my question, which was would a patient questionnaire give you an objective measure of whether or not mesh was shrinking or remaining inert?

MR. WALKER: Object to form.

THE WITNESS: It doesn't make -- I'm sorry, but the question doesn't make any sense because objective measures what is assessed by independent observer. What the patient says is subjective. So patient can't give objective because she's not going to go inside and measure, so that's something done by independent, someone not the patient.

BY MR. WOOL:

Q. So would you agree that a patient questionnaire cannot give you an objective measure of whether or not mesh shrinks in vivo?

A. Yes.

MR. WALKER: Object to form.

BY MR. WOOL:

Q. Now, are you offering a general opinion on the porosity or weight of the Prolift mesh?

A. Yes.

Q. And what's your opinion?

A. In what regard? Can you be more specific, please.

Q. Yeah. I guess let me ask, I guess, a different question. For the Gynemesh used in the Prolift, has the pore size remained constant?

A. So the mesh that --

MR. WALKER: Object to form.

THE WITNESS: The mesh that's used in Prolift is not Gynemesh, it's Gynemesh Prolene Soft, so it's Gynemesh PS, so can you again --

MR. WALKER: Could you clarify what you mean by constant?

BY MR. WOOL:

Q. So throughout your use of the Prolift system, has the pore size of the Gynemesh remained the same? Sorry, has -- okay, strike that, strike that. When you received the kits of the Prolift from Ethicon, the size of the pores of the Gynemesh prior to insertion now has

been constant throughout your use of the product?

A. The size of the mesh pore size is about 2.4 millimeters. There's no way any physician goes and starts measuring these pores and sees if it's constant or not. It is impossible for anybody to say whether it's constant or not.

Q. Okay. Let's see now, are you offering an opinion on the flexibility or stiffness of either the mesh in the Prolift or Prolift+M?

A. What -- how do you want --

Q. Let's see, I believe it's on -- let's go to Page 12 of your report. So at the second paragraph down, and this is discussing the Prolift+M, you're stating that the --

A. Yes.

Q. -- the longitudinal, and I'm quoting here, the longitudinal stiffness decreases allowing for the expansion of the neighboring viscera and, hence, potentially decreasing the potential risk of dyspareunia. So I guess what is the basis for that statement?

A. So this is what I initially mentioned, when I switched from Prolift to Prolift+M I think you had asked me why did I make the switch, and I told you that I was clinically hesitant to make that switch because I was

enjoying such great results with the Prolift. However, the structural properties of this, you know, the potential advantages, potential advantages, the key word is potential, were enticing enough to make the change, in that when the engineers told me that the lateral structural integrity of this mesh is preserved, that means its support should be good, but once Monocryl disappears, the longitudinal flexibility improves, that means it can stretch better vertically, then, as we mentioned, maybe that we have a better impact at sexual function, because sexual activity is more longitudinal, as the partner is going inside it's more of a longitudinal movement of the vagina. So then you think intuitively it makes sense. Until you actually put it into practice and study it over time, you never know, you know. So this is when we just got them, it was just out, so there's no way you can know until you've studied several women over a period of time.

Q. And have you conducted such a study?

A. Yes. So talking about my Prolift+M study, as you can see, if I could refer to that, which is Page 14, it's a prospective study on 157 patients, and you can see de novo dyspareunia was noted in 6 percent of 50 subjects -- in 3 of 50 subjects. The typically quoted

dyspareunia rate for mesh prolapse surgery has been between 14 and 36 percent.

Q. So I guess my question is is there an actual way to measure the objective lateral support of the Prolift+M mesh once it's implanted?

A. I don't know.

Q. Don't know, okay. And in your study, I guess -- strike that. So my question is your conclusions on the lateral support and/or longitudinal stiffness are hypothetical based on the results of this study?

MR. WALKER: Object to form.

THE WITNESS: It's longitudinal support and lack of longitudinal stiffness, so it becomes longitudinally flexible, not stiff, that's what the Prolift+M does. So what we then look at is when the engineers come up and tell us that, hey, these are the properties of this mesh, these could be potential advantages of the mesh, which is if it is longitudinally more flexible and less stiff, it may help with sexual function, and then we go back and do clinical trials and see is that true? And, sure enough, I did note that in my study that our incidence was 2.2 percent which is a very low risk of dyspareunia. Now, granted there was 157 patients prospectively followed up, you know, over a

period of a year. Still, it is a good number. Now, that doesn't -- what we look at is is there a clinical correlation, and that's really what matters. What is -- how do you know whether this lateral -- as you mentioned, can you objectively state that the lateral stability of this mesh can -- can you say that the lateral stability of the mesh, can this be objectively studied? Yes, in the sense that she doesn't have recurrence of prolapse or recurrence of prolapse is low. That means you know it's doing its job. So the reason why this mesh was altered was to see that can we maintain this support of Prolift that was very good, can that be maintained while trying to improve some of the pliable issues of the mesh so that it becomes more compatible with vaginal function such as intercourse. Could we, therefore, as stated here, some papers were saying 36 percent dyspareunia, some papers said 14 percent dyspareunia, can we start decreasing some of these percentages so that ultimately what I started as talking about outcome, can we do something which helps her, what she came for and prevent harm. So that's why I switched. And, yes, maybe it makes intuitive sense, but can I put it in clinical practice and does it come out so? And sure enough, you know, at least you have

less problems if that happens, and you have same success, you know, why not.

BY MR. WOOL:

Q. So I guess comparing the results that you've had in your studies with the Prolift versus your studies with the Prolift+M, I guess what I'm asking is are you attributing any better or the superior rates of de novo dyspareunia, et cetera, to the properties of the +M, to the properties of the mesh of the +M?

A. I don't think I've noticed the difference, and I can't really compare these two studies per se because they're not head-to-head comparisons. The only time I can really tell you apples to apples is if I'm doing a randomized clinical trial of Prolift and Prolift+M. But what this was, one was a retrospective study, which was the Prolift, and that's over 315 cases already done. The other was a prospective trial. They're two different study designs at the same time two different study periods, so it was not at the same time so I can't --

Q. Okay. So to be clear, I guess --

MR. WALKER: I'm sorry, could I just interrupt and ask was your question confined to the studies that he has done or --

MR. WOOL: Yes.

MR. WALKER: Or to the medical literature in general?

MR. WOOL: No, to his studies.

And so I guess I'll ask the question of do you believe that the medical literature in general shows that the mesh in the +M has a clinical effect on decreasing dyspareunia rates?

MR. WALKER: You mean as compared to Prolift or compared to what?

MR. WOOL: As compared to Prolift.

THE WITNESS: From what I recall, I don't recall any head-to-head comparison in a randomized clinical trial Prolift versus Prolift+M. However, I could state this: When the one-year Prolift+M trial was done, you know, they did say that the success could be a tad not as good as Prolift. However, it was just a one-year follow-up. So I look at it, you know, they are very much similar. So initially it was attributed that maybe Prolift+M is better, but there was not much difference. So when you look at cohorts studies done with Prolift, studies done with Prolift+M, nothing really stands out, you know, that, yes, it was a dramatic change, dyspareunia went down significantly or

mesh erosions disappeared, you know, nothing like that happened. So they are very much in the same ballpark. Now, maybe they could be -- and, see, when you come to certain subtle things, when the incidence of a complication is very low, so, for example, the incidence of complication of erosion was like 3 percent or 4 percent, you need a large sample size to see a difference, you know, so in this case there may have never been done large clinical trials comparing these two procedures at a time.

BY MR. WOOL:

Q. Okay. So I guess --

A. So can I say -- so my opinion is that there's essentially no difference clinically between Prolift and Prolift+M that I experienced.

Q. Okay. Now, did we say at the beginning that you're offering a general opinion on the design of the Ethicon Prolift or Prolift+M?

A. The kit, yes.

Q. Sorry, what did you say?

A. The mesh characteristics.

Q. Okay, the mesh characteristics?

MR. WALKER: When you say design are you talking about the mesh characteristics or everything

that goes with the kit?

MR. WOOL: Right, everything that goes with the kit.

THE WITNESS: Yes.

BY MR. WOOL:

Q. So you do have an opinion on everything that goes along with the kit?

A. Yes.

Q. Okay. And what is that opinion?

A. It depends upon the question.

MR. WALKER: For which product?

MR. WOOL: Sorry, let's start with the Prolift.

THE WITNESS. What specific question?

BY MR. WOOL:

Q. I guess where in your expert report is your opinion related to the design of the Prolift kit?

A. So from the -- it's more from the point of view of usage. So how does a Prolift kit respond in the human body. So when we talk about the Prolift kit it's -- there are two parts. One is the trocar, second is the mesh itself. We're talking about the trocars when looking at is there any complication that happens from that. So looking from that, you say, okay, was there

any specific injuries that happened because of insertion of these trocars in the human body. Number two, looking at the mesh itself. For the mesh, I'm looking at success and complications. So that's what. I'm not looking at how it is packaged, that's not my opinion on the packaging of the mesh. My opinion is it's used in the human body and the ease feasibility of maneuvering these instruments in the body.

Q. Okay. And I guess your opinion is that it's safe and effective?

A. Yes.

Q. Okay. And what is the basis for that opinion?

A. For safe and effective?

Q. Yes, of the Prolift.

A. It's my extensive clinical trial, I mean I have been doing this -- I was doing it for almost like four years and followed that after, and we have enjoyed unbelievable results with the Prolift system. At the same time, if you look at the medical literature, it abounds with fantastic results. It's not only about my experience, it's not that, okay, well, Khandwala, he's the only one outlier. If you look at the whole -- most of the urogynecologists using the mesh, whether it is in the United States, whether it is the Nordic countries,

whether it is in Australia, whether it is in -- not Australia -- Amsterdam, you know, the Withagen group, any of these physicians would tell you that from the literature that the success that they enjoyed was phenomenal.

Q. Okay. Now, if you look at Page 12 of your expert report, the last paragraph, you described this retrospective study with 315 cases.

A. Yes.

Q. Was that a published study?

A. No, we sent it for publication, and they asked for some alterations, and we waited for those alterations to happen, and now we're combining all these, the Prolift and Prolift+M.

Q. And where is the data for that -- or I guess strike that. First, what form is the data currently contained for that study?

A. It is in a spreadsheet, so Excel spreadsheets, and we have this whole data compiled in our practice.

Q. Okay. And have you provided that data with any of the materials that you've provided today?

A. No, not the data.

Q. Will you?

A. I could.

MR. WALKER: And let me just state for the record and interrupt you, Doctor, that I believe we have filed objections that relate to this, that those objections have been filed to the specific request in the Notice of Deposition that relate to what you're asking about.

MR. WOOL: Okay.

BY MR. WOOL:

Q. Okay. Let me shift gears for a second. Turning to Page 13, let me ask you about this study of the Prolift+M with the 157 consecutive subjects. Now, let's see, did this study just deal with mesh placed in the anterior compartment of the vagina?

A. No, this is anterior, posterior, and total. I'm sorry, what I was looking for is what was the breakup, and in the paper there is a breakup of how many were anterior, how many were posterior, and how many were anterior and posterior, called total.

Q. Okay. And, sorry, to go back just very quickly, the unpublished study that we were speaking about before, was that exclusively anterior?

A. No, this was anterior, posterior, and total.

Q. So both studies are total?

A. Yes.

Q. So just a couple questions about the numbers. You say -- and this is the second paragraph down on Page 13, that you started with 157 consecutive subjects.
A. Uh-huh.
Q. And then we go down to the second to last paragraph and we're down to 122 subjects.
A. So cystoscopy was performed in all eligible 122 patients. What that means is the patients who had a back wall repair, just a posterior vaginal wall repair with mesh, they did not need a cystoscopy, so you do not need to do cystoscopy. I did cystoscopy anybody who had an anterior wall repair or an anterior and posterior wall repair.
Q. Okay. And then, similarly, another question about the numbers, if you flip over to Page 15, the middle paragraph, you note that de novo dyspareunia was noted in 3 of the 50 subjects.
A. Yes.
Q. So how did we get down to 50?
A. So it depends upon how many patients were sexually active. So of all these patients who were in the study, 50 patients were sexually active at that time.
Q. So 50 out of the 157?
A. Yes, were sexually active.

Q. Is that correct?
A. Yes.
Q. And one more question.
A. So can I -- if you actually look at the paper, we have broken this down into a table which shows how many people were sexually active before, how many were not sexually active. We then looked at patients who are sexually active before, how did they do after the procedure. How many continued to be sexually active. How many became sexually inactive. Then we further looked at those afterwards who were sexually active, how many had pain, how many did not have pain.

On the other side, women who were not sexually active, we looked at how many of those women who were not sexually active before surgery became sexually active after surgery, and if so, how many of those women had no pain and how many had pain.

Q. So the 50 subject number on Page 14 includes women who were both sexually active before and after the --
A. It's after.
Q. Oh, it's only after?
A. Yeah, de novo dyspareunia.
Q. Okay, sorry, my apologies. Could we take a quick break.

(A recess was taken from 12:03 p.m.

to 12:28 p.m.)

BY MR. WOOL:

Q. Doctor, right before we took a break we were discussing your 2013 study on the Prolift+M.

A. Yes.

Q. Do you recall that?

A. Yes.

Q. So I just have a couple more questions regarding that study. Okay. So you -- and I'm on Page 13 of your expert report. In the second to last paragraph you note that there were no surgical complications beyond Dindo scale grade. So what is Dindo scale grade?

A. So the Dindo is a grading scale that was devised for any complications that happened. So 1 is a minor complication that does not need any intervention. Then 2 is if it needs an intervention in the office. 3 is if it needs an intervention in the hospital setting. And 4 is a major intervention. And I believe 5 is death. I don't exactly know, but that's what it is, it's based upon that, it looks at different aspects. So in this case as there were no visceral injuries, you know, so it was scale grade A may have been, I don't know --

Q. So if there were no complications on the scale at all, I believe 1 you described as a fairly minor complication,

so there were effectively no complications?
A. Correct.
Q. So that's a pretty impressive result, I assume?
A. Well, you know, it is if centers that have done this, I mean if you look at medical literature, also, there is a paper that was published from the Northwestern part of France, a person by the name Michelle Croissan, and the paper's name is by Laurant de Landsheere d-e L-a-n-d-s-h-e-e-r-e, and what he -- in his paper they had 521 patients that they followed up, and these were at least about two to three years out, and their risk of complication on bladder injury was .1 percent, bowel injury was like .2 percent, and their mesh exposure was 3 percent. So I think centers across the board that would do a lot of these cases, and most physicians who should be -- who are good at surgery usually have, you know, similar results with low risk of complications.
Q. Did -- and I'm not going to be able to pronounce the name -- the French study you described, was that a study of the Prolift+M?
A. It was Prolift.
Q. That was a Prolift study. Okay. And this is a question just in regards to the studies that you have conducted yourself, or strike that. Let me just go back to this

study. You were the only surgeon performing on this population of patients in this study, correct?

A. This, yes.

Q. Okay. And if you go back to Page 12, the retrospective study of from 2005 to 2009 using the Prolift, that was exclusively you as well?

A. That's correct.

Q. As the surgeon? Okay. And so I guess generally all of your studies or the three that -- I believe the three that you cite, you were the only surgeon involved in those studies?

A. I do have residents who assist me, and they may have done a part of it, but under my guidance. So if it was my resident or fellow, it would be under my guidance, so I was actively involved in the --

Q. So it's fair to say that all the surgeries were either performed by you or under your direct supervision?

A. That is correct.

Q. Okay. All right. So I'm shifting gears just a little bit. Now, are you offering an opinion on laser cut versus a mechanically cut mesh at all?

A. From the engineering standpoint, no.

Q. From any other standpoint?

A. I can tell you from the success standpoint, from the

clinical standpoint, yes.

MR. WALKER: Well, let me just interrupt. Are you -- what products are you referring to with that question, because all of the Prolift+Ms are all laser cut meshes.

MR. WOOL: Right. I guess just, you know, and I guess my question is just confined to is he planning on offering a general opinion as to the benefit of one over the other.

THE WITNESS: And I apologize, I am sorry, I keep forgetting I'm doing this report on Prolift and Prolift+M, because, of course, I'm a physician and I use slings all the time, and I'm very, very familiar with the TVT family, so when you mentioned that, automatically I'm thinking about the TVT group of family.

BY MR. WOOL:

Q. Right. So just for the treatment of pelvic organ prolapse.

A. Yes.

Q. Do you have an opinion generally on laser cut mesh versus mechanically cut mesh that you plan on offering for this litigation?

A. I don't think I've used -- I don't even know if Exair or

Elevate is a mechanically cut mesh, I'm not sure, from this litigation Prolift and Prolift+M, they're not -- it doesn't arise.

Q. Okay. So you are offering a general opinion on Ethicon's warnings; is that correct?

A. Yes.

Q. For both the Prolift and the Prolift+M?

A. Correct.

Q. Okay. And what is your general opinion, let's start with the Prolift, on the warning for the Prolift?

A. Can you specify, please.

Q. Sure. I guess is your opinion that the warnings for the Prolift kit are adequate?

A. Yes.

Q. And is your opinion that they are safe and effective or, sorry, strike that. Let's see, and for the Prolift+M, the same question.

A. Yes, adequate, the IFU.

Q. Okay. And let's see, and what is the basis for that opinion?

A. I have reviewed the -- if you're talking about information for use, I have reviewed the information for use and I looked at it, and I find that it is more than adequate.

Q. Okay. Bear with me one second. I'm going to hand you what we'll mark as 6 and 7, so this is the IFU for the Prolift, and this is the IFU for the Prolift+M.

KHANDWALA DEPOSITION EXHIBIT NUMBER 6,
GYNECARE PROLIFT
WAS MARKED BY THE REPORTER
FOR IDENTIFICATION

- - - - -

KHANDWALA DEPOSITION EXHIBIT NUMBER 7,
GYNECARE PROLIFT+M
WAS MARKED BY THE REPORTER
FOR IDENTIFICATION

THE WITNESS: So blend the Prolift and Prolift+M?

MR. WALKER: Well, just wait. He'll probably ask questions about each separately.

BY MR. WOOL:

Q. Okay. So looking at the IFU for the Prolift, are you familiar with this document?

A. Yes.

Q. And you've reviewed it before?

A. Yes.

Q. Okay. Now, does the document, does it warn that the surgery should only be performed by a experienced

physician or an experienced surgeon?

MR. WALKER: Object to form.

THE WITNESS: It basically, I don't think we need to see that. I mean when we look at an IFU from the surgeon and physician standpoint, we look at something that as a guidance. It's a surgeon's ability and credentials are not determined by the company. It is by the American College of OB-GYN or American Urology Association, and now the American Urogynecologist Society, and privileges at the hospital, that is what credentials a surgeon to use or not. So any surgeon who is credentialed to do these procedures is an experienced surgeon, you know, because that's what he, that person gets credentialed to do. So if they are credentialed, they can do the procedure, and it's not up to the company to state that, so I would not be looking at that information in an IFU, anyway.

BY MR. WOOL:

Q. Okay. And that statement is equally applicable to the IFU for the Prolift+M?

A. That's correct.

Q. Okay. And so you mentioned that -- so tell me about the credentialing process for surgeons. Just how does it work? How does one get credentialed I guess is the

question?

MR. WALKER: Are you talking about in general or at his specific hospital?

MR. WOOL: Let's talk about in general first.

THE WITNESS: So depending upon subspecialty, so let's say in my case obstetrics and gynecology, so first of all I have to go through a residency. Once I finish the residency, then I sit for a board examination, which is a written board examination and an oral board examination. And then I get -- I am conferred the degree of the fellow of the American College of OB-GYN. And once I have that credential, so then I'm M.D. FACOG, once I become that, I apply at -- for hospital for that particular specific hospital privileges, and it could be right from vaginal deliveries to Cesarean sections to hysterectomy. And then the hospital has a board, and the medical professionals who sit on the board, they look at what are the privileges a doctor is requesting and is it concordant with their practice and their field.

So if I'm applying for amputation privileges, I'm a physician, I can potentially do amputation, but that is what -- hospital would not give me privileges because I am a gynecologist. So if I'm applying for

privileges for vaginal surgery, then they have certain requirements.

Then it goes a step ahead where if they're looking at certain things like robotic surgery, and it's part of -- it's hysterectomy but done through the robot, and if that is so, then there may be certain specific regulations or requirements for each credentialing committee which is very specific to each hospital. So, for example, my hospital may say that if you want to do robotic laparoscopic hysterectomy, you need to be proctored for 10 cases. In Denver they may say you need to be proctored for 15 cases. So that's a different thing.

Same thing with vaginal mesh, say for vaginal mesh you need to be proctored for these many cases, so they may be -- the credentialing requirements vary from hospital to hospital, from state to state, and that is very subjective to each individual place.

BY MR. WOOL:

Q. Okay. So let's just focus on, I guess, the hospitals where you perform prolapse surgery using mesh. What is the credentialing process there? Is it essentially what you just described?

A. So initially, I mean, well, when I applied for the

privileges way, way back, you know, at that time I was already a fellowship -- had done a fellowship and a subspecialty in urogynecology it used to be called then, and so that itself gave me the additional, you know, education and certification to apply for certain things such as vaginal mesh surgery. Of course, I had gone to a cadaver course, I had been proctored there, and then with the overall knowledge that you possess as a gynecologist and having done these surgeries, you know, they allow you to do this procedure so you get credentialed to do it. So that's how I got credentialed to perform these cases.

Q. Okay. And I believe you've already answered this question in some way, but to be clear, kind of across the country there isn't a uniform system for credentialing physicians to perform either surgery with the Prolift or the Prolift+M, is there?

A. At this moment, of course, the products don't exist, but when they were there, yeah, it was -- no, it was very individualized how every hospital and the hospital committee behaved.

Q. Okay. And would a physician ever be able to legally perform pelvic organ prolapse surgery at the time with either the Prolift or the Prolift+M if they were not

credentialed?

MR. WALKER: Object to form.

THE WITNESS: I don't think they would be allowed in hospitals, and if they're practicing in a hospital, if they are not credentialed to do, but I don't know if they're specific to that, so, for example, they -- the credentialing committee does not go very specific to a particular mesh device, so it won't say you can do Prolift but you cannot do Prolift+M or you can do Elevate but you cannot do Prolift. What they may credential to you is that you can do vaginal surgery for prolapse with or without augmentation, a very general term, and then it is up to then different specific things that, you know, what may be required that a physician may have to do like go for a cadaver course, and I think ultimately because the physicians will champion this, so if I want to do something for my patient, I'm not just going to put something in my patient that I don't know how to do. I may be credential at a hospital to do vaginal augmentation surgery, but tomorrow if there's a new technique that comes out, I will put in the due diligence to learn the new technique, the process, how it works, what is the science behind it, what is quoted in literature, and

that's the main thing we fall back on, what is the literature? What has been published? What is out there? What is the information? So most of my colleagues including myself count on in my case, yeah, maybe it's a unique situation that I do have clinical studies of my own, but that's not all I count on. I count on my studies and what has also been published in literature what I discuss with my colleagues at conferences, in the summit meetings that I mentioned, that plays a tremendous role in the overall formation of should I do this or not.

Once that has been achieved and once I've realized that, yeah, this is a product that I have talked to my colleagues, I have read the literature, I've discussed with others, and it makes sense, then I would be able to use it, you know, so it's impossible for a credentialing committee to be specific and say you can only use this, not that. So they may just say you can use a robot but not for which type of operation. Can I take the ovary out? Can I take the tube out? Can I just take half of the uterus, full uterus? Well, that's left ultimately to the physician.

BY MR. WOOL:

Q. Okay. And so the credentialing process for pelvic organ

prolapse surgery would essentially be uniform across -- not across the board, sorry, strike that. A credentialing process would allow you to perform surgery for prolapse generally?

A. Yes.

Q. Okay. And it wouldn't say you can't use this device or you can't use that device?

MR. WALKER: Object to form.

THE WITNESS: They cannot -- usually when a credentialing group meets, it's like a general group, it's a primary care physician, there may be some other there's on it, so they are not even well versed in that special, each mesh design, so they don't look at it that this is one you can use, same thing when a new instrument comes out through the robot, when the morcellator came out, they can't say, oh, you cannot use it.

So then they go by you are a gynecologist, you practice in the vagina, this is what your specialty is. What are you talking about? What privileges are you requesting? And they look at and why? So they get documentation and then they understand that that makes sense.

The knowledge base that I possess is much more

than what the credentialing committee has, but then they set up some guidelines that we essentially follow, but it's more guidelines that are usually general but not specific to one product.

BY MR. WOOL:

Q. And so you had said before, and I just want to make sure that I have this correct, that if a physician is credentialed, that they're sufficiently experienced to use the device, whether it be the Prolift or the Prolift+M, correct?

A. No, so the credentialing process, as I mentioned, it's more of a process that involves that can this person use a vaginal augmentation. So suppose if I apply and say I want to do vaginal augmentation surgery, and now there is a new mesh on the market, you know, and that I want to use, they will not object. The credentialing committee doesn't have to say, okay, give me information about this particular mesh. Now, that's up to me as an individual to learn about what this mesh is and why am I using it.

Q. Okay. And as we discussed in the Instructions For Use, there isn't anything in there about restricting use to experienced physicians?

MR. WALKER: Object to form.

THE WITNESS: That doesn't have to be, because it's up to the physicians, and it's not -- the company cannot restrict or allow, it's not up to the company to do that, it's up to the physicians, so it's up to us and our societies to manage that, you know, and to police that, not -- a company cannot say you cannot use it. Once a physician is a credentialed gynecologist, he or she can use these products, now it's not up to the company to control that.

BY MR. WOOL:

Q. Okay.

A. So, in other words, if we are saying, okay, you can't use it because you only have done five, it's not for the company to decide. It is for the credentialing committee of the hospital or the Department of Gynecology or usually the physician themselves.

Q. Okay. So if you turn to Page 18 of your expert report, I'd like to direct your attention to the line at the top of the page where you say that vaginal prolapse surgery is clearly a complex surgery and should be performed exclusively by surgeons who are experienced in this. You read that?

A. Yes.

Q. So what is the criteria for experienced surgeons?

A. So the main thing is understanding the anatomy, and that's very important, so this is -- the word is I have put vaginal mesh because I'm talking about mesh, but this mainly alludes to vagina prolapse surgery. It's different. You know, when you go from above, the anatomy looks very different, looks very normal. When you're going from the vagina, it looks almost opposite, you know, you're going from below up, so it is very complex, plus you're working in a tunnel, and it's very hard to go from a tunnel into these deeper spaces. Then, again, you are doing a lot with palpation, it's almost like Braille, you're palpating these things, you're feeling it rather than actually looking and seeing it. So there's a lot of experience that a surgeon has to gain over time to understand this. So the main -- if they understand anatomy, then they understand the breakdown of anatomy that happens with prolapse and, then they have to understand the alterations of anatomy that could be specific to that particular person. Could that change how the blood vessels are, you know, where things are with the uterus coming, for example, when the uterus is inside, the tubes that drain both kidneys called ureters, they are proper. When the uterus is completely outside, the

ureters can get kinked, and they are very, very low. In fact, with complete prolapse, the ureters are outside the body, so that is something that a surgeon needs to know, that anatomy changes as these pathologies happen, so that's very important.

So the main focus, it's complex because they absolutely need to know the anatomy, the breakdown of anatomy, the pathophysiology, and the surgical variations through a tunnel. And that is -- it's often labeled as what we call no incision natural orifice surgery because you're going from the natural orifice. However, it's complex, because you're going from such a small opening, and you're doing such a large operation through a small opening which was previously done by cutting the belly open.

Q. So how does a surgeon gain this understanding of anatomy?

A. So they -- first of all, it's in medical school understanding what anatomy is, then going through residency where they learn how to assist in these procedures, they learn how to do these procedures, and that they go out and practice. So not everybody has to be someone like me who's fellowship trained. You know, most of the physicians who are using the mesh are normal

OB-GYN physicians and urologists who are very good surgeons.

So how do you become a good surgeon, if not by doing a fellowship, you do not have to do a fellowship. You can be out there, you understand this, and you put in due diligence, take time, understand the problem, figure it out how a patient is behaving to this, follow these patients over time, and see how you can improvise.

Q. So -- sorry.

A. So it is this entire process, including learning from your peers, going to conferences, being involved in these societies, and then reading literature, you know, where they tell you about how to -- like what are the monogram on Prolift is a perfect example. You know, when the IFU came out it was just some information, but the monogram when it came out, that is written by physicians for physicians to understand these nuances. So we have gone through these. Now you have these experienced doctors who are doing a lot of cases, they have learned this. How do you now explain these pearls to everybody? So that's why this monogram was put up together and that goes over these pearls, different things, you know, what can be done, what -- how you do this, what have been the modifications since Fatton, you

know, described this with the Prolift beginning and how we have changed.

MR. WALKER: Just for clarification, when you're talking about the monograph, you're talking about the Prolift surgeon monograph?

THE WITNESS: Yes, the Prolift surgeon monograph.

BY MR. WOOL:

Q. And you mentioned what I think you described as a normal OB-GYN. According to your definition, would somebody like that meet your definition of an experience?

A. Absolutely. The experienced is more about someone who has gone through these courses, the steps. One is understanding the anatomy, and understanding what has broken down, then understanding what happens with surgery, reading the literature, making awareness -- becoming aware of what the society that deals with pelvic floor dysfunction is talking about, going to conferences, and then practicing on their patients and seeing what happens over time with their own patients and own interaction.

The key is what does that particular person note in his or her experience? And that's even what the FDA said, that it's so different, and I cannot globalize

it because in one surgeon's hands the success may be different, in someone else it's different, so that's why it's important for each surgeon to understand what is my story and how am I doing with my cases. So if someone has done this, it doesn't matter whether he is board subspecialized in urogynecology or a generalist OB-GYN or a generalist urologist, it doesn't matter. That person, I'll call him or her experience.

Q. So you mentioned part of gaining this experience was practicing on your patients. So has somebody who has not performed any of these procedures before on their patients, can that person be experienced under your definition?

A. Well, eventually someone has to start somewhere, so, first of all, when you go in, you go to cadaver course, and then -- so typically the way it unfolds --

Q. Let -- I guess, I think my question's a little bit simpler than that. It's simply can somebody who has not practiced any of these procedures on their patients be considered or do you consider that person to be experienced?

MR. WALKER: Object to form.

THE WITNESS: If a person has never done vaginal prolapse surgery, no, they cannot be

experienced, because someone has to have done vaginal prolapse surgery before they get into using the -- doing any of these -- of prolapse surgery for that matter.

BY MR. WOOL:

Q. Okay. And to clarify your opinion on mesh prolapse surgery as it relates to both the Prolift and Prolift+M, it's your opinion both in your report and today that it should be exclusively performed by surgeons who are experienced?

A. Yes. But, again, as I defined experienced surgeons. So my definition of experienced surgeon still stands. It's an experienced surgeon, and that's key. It should not be someone who just does one case and never does anything about it at all. It should be someone who is following the literature, under the medical literature, reads what's out there, goes to the societies, goes to the conferences, and this is where if we want to be involved -- if they want to be involved in this, they have to become experienced surgeons to do this. So that is what I personally feel in my opinion the main thing that mitigates the risk of complications is my definition of an experienced surgeon. So I would say, I should take the word out surgeon, I would say experienced physician or experienced clinician. This is

not just someone who goes as a technician in the operating room and operates. This is someone who puts in the extra effort to understanding what is the information? What is out there? What is the literature? What are people talking about? It's not just, you know, me doing one case and just doing the technical repair.

MR. WALKER: And I object to the form of the previous question. I just didn't want to interrupt him.

BY MR. WOOL:

Q. Okay. And so I guess my question would be if we are talking about an inexperienced physician or surgeon -- strike that. So do you have any opinion on the data for the Prolift and the Prolift+M as they relate to inexperienced surgeons?

MR. WALKER: Object to form.

THE WITNESS: As I told you, I don't think that this should be something which -- this should be done by experienced surgeons, and I think people who have done is the people I know and I've read the literature, these are people who are experienced surgeons, so from that definition I talk about, so I don't think -- I don't know anything like that, I'm sorry.

BY MR. WOOL:

Q. So when you -- when a patient presents to you with pelvic organ prolapse, I guess how do you assess the risk benefit profile of that patient?

A. So when a patient comes in and she says -- and then the key thing as we talked earlier on, most important thing for me is what is she coming with. So those validated questionnaires will explain to me and summarize as to this is my problem. So let's assume she has a complaint of a vaginal bulge, and she's really bothered by the bulge. Then what are the other aspects which are important? You know, what are the associated factors such as her age, is she menopausal, is she on estrogen what is her weight, is she a smoker, has she had prior surgery, does she have a uterus, does she want to keep her uterus, does she have any other abnormality with the uterus, is she bleeding heavy or something else going on, so there are so many factors that play a role in deciding what to do.

Then we do certain tests to see whether she has -- she is emptying her bladder well, does she have occult stress incontinence, we look for that, is she complaining of fecal incontinence, we assess that, we look at the entire pelvic floor.

Once you've done all that, and then we sit down and talk to the patient and say, okay, what is -- this is the information. So the information that we discuss with the patient is giving her the evidence, telling her what is the information that exists? Not just only my information, that's also important to her, but I give her overall information, so this is the information in the medical literature.

So let's say if I am proposing vaginal mesh surgery to her, I would say this is information in the medical literature, this is what has been documented, this is also my experience, and this would be the information for that. Then I would tell her the same thing about pessary, this is the good with the pessary, this is the bad thing about the pessary, and I make them understand that, you know, if they have to analyze -- ultimately, my ultimate goal is to empower that woman, that patient of mine, this lady sitting in front of me, empower her with the knowledge in a colloquial language that she understands exactly what she would want, not what I am going to force and force her to undergo. So once she's heard this, now she has clear information that we've given her what we call nondirective counseling, so without bias I give her the information.

Once you've laid it, now she has the facts. So I tell her forget about everything else, what I've given you are the facts and here's the literature to support. We give them the white paper of the FDA, we give them the FDA up classification which recently came out, we gave them our results, we give them what is out there in a booklet that we give the patients, so they have enough information, and I make them understand that the ultimate decision is based upon what they want. I'm there to guide them and direct them, but I am not going to force them one way or the other.

So even sometimes they ask me, so if it was your wife or your mother, what would you do? I say it's different, their body frame is different, you are different. I'm going to go over your risk profile and say what is your age, what is your BMI, are you menopausal, are you a smoker? I look at all those factors and come up with a risk strategy based upon that and come up with what we call a balance scale, risks to benefits. So which way does this tip? And then if it tips in favor of benefits of doing vaginal mesh, that's what we do. So based upon that. So it's a very detailed counseling, which most of us agree, and if you look at literature, also, most -- if even if the society

guideline statements, they'll tell you that it's important to discuss with your patient, explain to the patient what's going on. So this is not exclusively to what I do, this is what's done by my peers as we go to societies and we talk to my colleagues, they say the same thing, that's what they do extensively, and they discuss more with the patients and tell them.

Q. Do you believe that manufacturers of medical devices have a duty to warn physicians of adverse events?

MR. WALKER: Object to form.

THE WITNESS: It's up to the physicians, I mean if there is -- ultimately it's up to the physicians because we would know it, what's going on, because I would see in my practice if something was happening, but if there's something bad happening with a particular product, yes, they should inform the physicians.

BY MR. WOOL:

Q. Okay. Do they have a duty to provide proper Instructions For Use?

MR. WALKER: Object to form.

THE WITNESS: Instructions For Use are written for physicians and for -- if they are -- ultimately it's, you know, it's based upon my experience as a surgeon and what we discuss and what we find out, my

colleagues in discussions and the medical literature that exists on this particular item, so let's be specific, let's say for Prolift, so what is out there? What is literature? What do my colleagues say? What do we discuss in conferences? What is my own experience is what dictates more, you know, than the IFU.

I can tell you the IFU is a guide. I can almost guarantee you that nobody sits with the IFU in the OR and goes through it step by step. Maybe we read this once, maybe couple of times, and it's not something that we -- it's like we have to study it and memorize it.

BY MR. WOOL:

Q. So you're saying you don't think that Ethicon needs to provide, I guess, accurate and correct Instructions For Use?

MR. WALKER: Object to form.

THE WITNESS: It's -- what I would look at it from this -- let's be more specific, in looking at the IFU, this IFU is more than adequate when looking at the Prolift IFU, so there's no point, other than conjecture.

BY MR. WOOL:

Q. So if it -- strike that. Okay. Do you believe that medical device companies such as Ethicon have a duty to

provide contraindications for use?

MR. WALKER: Object to form.

THE WITNESS: They can state it. However, a lot of that information we would know as physicians, and a lot of that information we would get from our own colleagues and discussing with our colleagues and understand. I mean this is nothing that -- for example, the contraindications for a physician are quite obvious. We would know what is contraindicated. I think it's important that whether it is done for a vaginal prolapse surgery with native tissue repair or whether it is done for -- with an augmented procedure like mesh, not a whole lot changes. It's very obvious, you know, so nothing much -- maybe it says pregnancy and child bearing, but short of that, patient on anticoagulation, you know, she should not be on a blood thinner, well, that's obvious to a physician, that should be there, anyway. So I don't think that we would really look at every word and follow that; we know ourselves what should be there.

BY MR. WOOL:

Q. Okay.

MR. WALKER: David, let me just put on the record we've gone over the three hours, and you've got a

total of five for Prolift and Prolift+M, and Dr. Khandwala's report encompasses both into a single report, and you've asked questions about both up to this point in time, so I just want the record to reflect that we'll be doing a five-hour deposition that covers both products; is that --

MR. WOOL: Yes.

MR. WALKER: Are you in agreement with that?

MR. WOOL: Yes, that's my understanding, and we are in agreement about that.

BY MR. WOOL:

Q. Okay. So is it your opinion that Ethicon mesh, either the Prolift or Prolift+M, or let's just start with the -- scratch that, just the Prolift. Is it your opinion that the Prolift is appropriate for patients with prolapse, say, lower than stage 3, stage 1 or 2?

A. It is -- as I mentioned, it's all -- the Prolift is just a device, it's just a mesh, it's an augmentation procedure. So let's say a patient has stage 2 prolapse, and I open up the vagina and I find that there is nothing, there's no fascia at all, then absolutely I would use a mesh. So this is -- my ultimate goal, and that is same thing as goal of my colleagues, is that we want to give the patient the best shot at the first

time. The problem with recurrence is then you'll end up with more complications. So if it turns out I can do fascia repair, just like as we mentioned, with a Stage 2 rectocele, if I did a fascia repair, there is good fascia there, there is evidence to show, as I mentioned in my report from Chris Maher, the 2011 Cochrane analysis, that the back wall repair can be -- has good results if done with native tissue. However, if I go with that intent, and I open up the vagina and I find that there is nothing there and it is a Stage 2 prolapse, there's just nothing I can put together, then what am I going to do? Am I going to just put nothing to nothing? And I don't think that's ethical from any standpoint. Then I would fall back on my experience, the experience of my colleagues, and what we've read in the literature to say yes, it does help. You know, even just looking at a Stage 2 rectocele, it would help from that standpoint just as -- when I talk about medical -- this is -- I'm not just talking about my results, I'm talking about results from the medical literature which talk about like the Withagen paper from Amsterdam, you know, which basically showed high success with placement of a mesh even for the posterior compartment.

Q. So do you think that prolapse severity should be listed

as a contraindication at all?

MR. WALKER: Object to form.

THE WITNESS: Contraindication for what?

BY MR. WOOL:

Q. So the severity of the prolapse, should that be listed as a contraindication on the Instructions For Use?

MR. WALKER: Same objection.

THE WITNESS: I think it's not up to the company to state that. I think it's up to us as physicians, and when to use it and when not to use it. So I would think it would be opposite, as a physician I would say that the larger the prolapse, the weaker the inherent and native tissue, so I absolutely want to augment that, you know, if that were to be the case. But it's not -- I think it's ultimately the medical literature. You know, my clinical experience is going to dictate how I'm going to manage that patient, and it's very much individualized, that's the beauty of medicine, what I really enjoy about it, it is tailored to even individual. There cannot be a cookie cutter approach. There could be one patient or the other may have similar stories, similar age, similar medical background, but a totally different outcome.

BY MR. WOOL:

Q. Okay. So the when a patient presents to you and you're thinking about providing them with surgery for pelvic organ prolapse using mesh, when you counsel them, what are the possible complications that you counsel them about?

A. The main complications, it doesn't really change when I talk to them about mesh or nonmesh. Most complications are the same. So there is nothing different I would counsel. So my main counseling, whenever I do surgery of any type of surgery, my counseling is bleeding, infection, and injury, so these are the three basic things that cover a lot. But then we speak about, you know, there could be narrowing, maybe some scar tissue in the vagina while you're doing the suturing, and especially when using her own native tissue, when you're trying to put things together, the big concern is we try to avoid and trim the vagina.

There is a high incidence of dyspareunia with native tissue repair, also, so I cannot say that that won't happened. So I tell my patients that -- essentially when I look at mesh versus nonmesh, there is no specific complication I would tell them. It is different.

Q. So there are no complications that you would advise patients on that are different from mesh versus native tissue repairs?

MR. WALKER: Objection.

THE WITNESS: Correct. So when looking at -- if I am repairing prolapsed native tissue repair versus mesh, there is no complication that is different between the two from -- as a complication, so complication due to the mesh, which is exclusive to the mesh, there is none, according to me.

BY MR. WOOL:

Q. Will you list the complications, and I know you did that a little bit, but I think there was some overlap, so just for clarity, all of the complications that you would counsel a patient on strictly for mesh.

MR. WALKER: Object to form.

THE WITNESS: I would counsel a patient for vaginal surgery, as I mentioned, whether I am doing native tissue repair or mesh, it doesn't change, but the complications I tell my patients are, one is bleeding; second is bleeding associated hematoma; third is injury to neighboring organs; fourth is infection; fifth is pelvic pain; sixth incontinence, and there are some others. So basically I don't -- I tell them about --

the most important thing, what is different from a paper like this, an IFU anywhere else as compared to what we do is we put things in perspective.

If you take a vitamin, also look at the PDR, and you look at the complications and the side effects of a vitamin, you won't even take a vitamin. Let me give an illustrative example. Ciprofloxacin or Cipro is one of the most potent antibiotic for a bladder infection. So if you have a bladder infection and you go to your doctor and he gives you Ciprofloxacin, he'll say, you know what, this is great, it's one of the best antibiotics. However, the red box warning on the Cipro is it can cause your tendon rupture, so Achilles tendon can rupture, and then you are walking with a splint on a walker for like six -- three to six months. If you knew that and then say, oh, my God, I don't want to take this antibiotic, that's when you go with the risk benefits. What we explain to our patients is the benefit outweighs the risk because we put things in perspective. What is the likelihood. So it's not just about enumerating all these complications. It's explaining to them the likelihood of this happening, putting things in perspective that what -- the likelihood of this chair breaking down exists, but what is -- the possibility

exists; what is the likelihood of it happening? That's how I explain to my patients. So it's not only enumerating all these complications and throwing at her and saying this is the laundry list of all your complications and here you go. It's -- what we do is we put it in perspective.

BY MR. WOOL:

Q. Okay. And is that answer equally applicable to both the Prolift and Prolift+M?

A. Yes.

Q. Okay. And so let's try to get into some of the specifics of each. So for your opinion that the Prolift is safe and effective, I guess looking at the data in your expert report, what studies specific to the Prolift form the basis of your opinions?

A. The main -- right from the start, right from Fatton, F-a-t-t-o-n, the French, the TVM group, you know, to the different publications from -- you can quote Caquant, C-a-q-u-a-n-t to Landsheere, L-a-n-d-s-h-e-e-r-e, to the group from Amsterdam Withagen, W-i-t-h-a-g-e-n, and Vierhout, V-i-e-r-h-o-u-t and Milani, M-i-l-a-n-i. So those were the -- and the main group was a Nordic group studies, which are Alterman, Daniel Alterman, fantastic paper, it was randomized clinical trial which was

published in the New England Journal of Medicine, one of the best studies done on the use of Prolift.

Q. So all those studies that you enumerated are exclusive to Prolift?

A. Well, some of these guys have also done studies with Prolift+M, but they have done predominantly studies on the Prolift.

Q. So I guess I'm asking you to specify the studies that you believe show the safety and effectiveness of the Prolift.

A. Yes, these are the studies, what I quoted were -- most of them were Prolift.

Q. And the same question for the Prolift+M, what studies do you believe prove the safety and effectiveness?

A. So I don't know if I added in, but I should add my paper, too, for the Prolift and my own clinical experience, which is also important. And the second from the Prolift+M, again, one is the Milani paper which was published, and then it was followed by the group Withagen and our paper and the Lusante had a paper that was published with Van Raalte, R-a-a-l-t-e. So these are the different papers that are published and, of course, that's what's published, but then, again, discussing at meetings when we talk, when we used to go

to the summit meetings, the Ethicon summit meetings when we met my peers and sit down at round tables and discuss and say, hey, how are things going, what did you find, and, you know, that is something that we literally fed off, you know, we enjoyed going to the summit meeting. It was not because it was a great place that we were going to sponsored by Ethicon, but it was more to get involved and brainstorm. And that was the most important experience, the going and networking is where you really learn a lot and, of course, reading the medical literature.

Q. Tell me about these summit meetings. How often would they occur?

A. They were happening once a year, so Ethicon would have the summit meeting of physicians who are doing this, and I don't know what criteria they would use, but we would all get together, and then we would have some general session talks, and they would say, okay, what is the literature, what is going on? And I had, for example, presented a paper on our Prolift+M data. Then we had breakout sessions, and in breakout sessions it would be more of a, you know, one of the persons starting a discussion. So I had, for example, once led a discussion on TVT Secure, and I stood up, and I said,

okay, guys, what do you think, what is going on? So it's more of a -- it is not a unilateral talk and a discourse. It was a partnership, it was a communication, it was a conversation. So we then understood what was going on and then figured out, and the company had people sitting in the back taking notes as to what are the issues, what are these doctors talking about, what are the goods, what are the bads, so it was a great thing for us as physicians.

Q. Did Ethicon pay for the physicians to attend the summit?

A. Yes.

Q. Did they pay for the lodging of the physicians at the summit?

A. Yes.

Q. Was there any other financial benefit conferred by Ethicon on the physicians other than travel and lodging?

A. No.

Q. Okay. Now, are you offering a general opinion on Ethicon's training of physicians?

A. Ethicon doesn't -- I mean I don't know -- are you talking about cadaver -- what do you mean by that?

Q. Well, we can talk about that in a second, but I guess are you offering a general opinion on any of the training that Ethicon provides to physicians regarding

the Prolift or the Prolift+M?

A. See, I don't think that is -- to me, the main training comes from us, we teach our peers, so it is how do we proctor them, how do we teach them at these courses and when they come to learn from us. Plus, the training is done individually. I want to go, I want to do something, I'm not going to count on the company to tell me, hey, do this or go here. I want to figure it out for myself. So I think it's more individual, more inherent to our group, and that's what physicians do, you know, we sort of link up and talk about these things.

Q. So it's fair to say that you're not providing an opinion one way or the other on --

A. Yes.

Q. Now, are you offering an opinion on pelvic pain associated with transvaginal mesh repair?

A. Yes. Let me say an opinion, whether it is associated or not is what the opinion is. My opinion -- the premise is pelvic pain is not because of mesh, that's my premise. Yes, on that I'm offering an opinion.

Q. Okay. And I know you just stated that, but, once again, your opinion is that -- and I don't want to characterize this inaccurately, but that pelvic pain is not

associated with mesh?

A. Correct. And this has also been published by a paper by Niemenen I mentioned -- I'm sorry, Nguyen, N-g-u-y-e-n and Brunett, and they published a paper where they use a mesh versus non-mesh, and they found that in patients that had a mesh there was significant improvement in pelvic pain as opposed to women who did not have a mesh and had native tissue repair. This is a randomized clinical trial.

Q. Are there any other studies that help form the basis of that opinion?

A. Yes, there's the Niemenen paper I just mentioned. So, now, that paper basically is a three-year follow-up, and what they found was that the incidence of dyspareunia was lesser in patients who had the mesh as opposed to not having the mesh. And I think there's one other paper which basically shows similar results, I think Sivasiaglu, S-i-v-a-s-i-a-g-l-u.

Q. Okay. And do you have any opinion on chronic pain being associated with mesh?

A. Mesh does not cause chronic pain; that's my opinion.

Q. And is that based on the same data that you just enumerated?

A. Yes, and there is some more information, also, pelvic

pain, and that -- and my own -- and so that's -- the literature, I think it's -- I can't exactly remember what the other article I was thinking about, but it's also based upon my clinical findings, so we did not see an increase in incidence of pelvic pain.

Q. Okay. Now, the studies that you described a moment ago --

MR. WALKER: Can I just ask you in terms of those questions about whether or not mesh was associated with pain or chronic pain, are you -- were you asking that in reference to both Prolift and Prolift+M?

MR. WOOL: Yes, and I'll clarify that.

And your opinion is the same for the Prolift?

THE WITNESS: Yes.

BY MR. WOOL:

Q. And the same for Prolift+M?

A. Yes, that it does not cause pelvic pain nor chronic pelvic pain.

Q. So for the studies that help form the basis of that opinion, do the studies limit the results to experienced physicians?

A. I don't --

MR. WALKER: Object to form.

THE WITNESS: I mean I don't know these

physicians, I don't know what their experience is, so I can't tell you. I just look at the medical literature and look at the study design. I don't really look at the qualifications or what these physicians credentialed are or how old they are or how many years they're working or experience. I look at, you know, what is the study design. So and based upon the study design, I say, okay, does this study make sense, and I look at the results once the materials and method make sense.

BY MR. WOOL:

Q. So when you look at complication rates for a number of these studies, you're not necessarily looking to see whether the physicians meet your definition of experienced or not?

MR. WALKER: Object to form.

THE WITNESS: Based upon maybe the publications, that's the only thing I can look up. I suppose if you have someone like Daniel Alterman publishing, so you know, well, at least from the publication standpoint and the study standpoint, I mean it's a powerful group, it's a very powerful Nordic group. So many of these are multi-centric studies, so now you go through a group which is based out of Amsterdam and there's this group which is the Withagen/

Milani group, then you look at the Nordic group, which is the Alterman/Elmer group, E-l-m-e-r. So you look at these groups, you can say, okay, well, these are big groups, so hopefully you think that, you know, they have good experience. But, otherwise, it could be a single person like me, I have a paper out, so nobody can look at my paper and say is this guy experienced or not, but they can look at the quality of the study, and they realize that, well, this is a well done study, there's a prospective study and patients followed up, you know.

BY MR. WOOL:

Q. But for your study as an example, could somebody look at your credentials and say this guy's experienced?

A. Yes. Well, they can look it up --

MR. WALKER: Objection, form.

THE WITNESS: -- on the American Urogynecology Society website, but I don't know what else further they can look at.

BY MR. WOOL:

Q. Now, are you offering a general opinion on dyspareunia associated with pelvic organ prolapse?

MR. WALKER: Could you clarify?

MR. WOOL: Sorry, I'll clarify it.

Are you offering an opinion that the Prolift

does not result in higher rates of dyspareunia compared with native tissue repairs?

THE WITNESS: Prolift does not cause more dyspareunia than native tissue repairs, that is correct. In some cases Prolift may have lower risk of dyspareunia, also.

BY MR. WOOL:

Q. Okay. And the same question with the Prolift+M?

A. Yes.

Q. Okay. And what's the basis of that opinion?

A. So that was a randomized clinical trial that was again done by this group from Amsterdam who looked at mesh versus no mesh, and they found that there was no difference in the dyspareunia rate in that group.

MR. WALKER: I'm sorry to interrupt. Could we break that down between Prolift and Prolift+M, just so that it's clear.

BY MR. WOOL:

Q. Yeah. So the same question with strictly Prolift.

A. Yeah. So Prolift, in both Prolift and Prolift+M, my opinion is that it does not lead to dyspareunia, the mesh itself, so -- and that is based upon just not my -- it's based upon my experience, what I've read in the literature and what I've discussed with my colleagues at

meetings, and this is very typical. It's, in fact, even listed in the 2016 Cochrane review by Chris Maher, 2015 Cochrane review, and that -- I think it's 2016, I'm sorry, it's 2015 or 2016. So in that review, what he says is that there is nothing specific, in that article they say that there is no difference in pelvic pain, dyspareunia, or anything else between the mesh versus nonmesh. The only thing that they say is exposures happen in mesh, they don't happen in native tissue repair.

BY MR. WOOL:

Q. Okay. And, I'm sorry, the Cochrane review that you're describing, am I incorrect in thinking that that's the one that looked at the Prolift+M?

A. The 2016?

Q. Were you describing the 2016 one?

A. The 2016 one.

Q. Okay. And --

A. Now, I think they looked at Prolift.

Q. Okay, that one was Prolift. Okay. So let me see. Sorry, did I ask you about -- the same question with the Prolift+M?

A. Yes.

Q. Okay. And same question, are you providing a general

opinion on dyspareunia associated with sacrocolpopexy?
A. No.
Q. Okay.
MR. WALKER: Are you asking whether or not he's going to opine whether there's a greater rate with that procedure versus -- Prolift or Prolift+M, or whether or not it can actually happen at all with that procedure?
BY MR. WOOL:
Q. Right, so to clarify -- I'll move on to a different --
A. The only abdominal sacrocolpopexy paper was the CARE study, the C-A-R-E study, and in Nygaard I don't know if they looked at dyspareunia as a variable, so I'm not sure, that's the only thing I can tell you.
BY MR. WOOL:
Q. Okay. So --
A. N-y-g-a-a-r-d.
Q. So I guess, going back, are you offering an opinion as to the Prolift or Prolift+M and sacrocolpopexy?
MR. WALKER: Object to form.
THE WITNESS. In what form?
BY MR. WOOL:
Q. Sorry, okay, let's just strike that and move on. Okay. Are you offering a general opinion on nerve damage

associated with pelvic organ repair from a transvaginal implant?

MR. WALKER: Object to form.

THE WITNESS: So Prolift/Prolift+M does not cause nerve damage.

BY MR. WOOL:

Q. Okay. And what's the basis for that opinion?

A. My own experience, because if look at when you -- again, it's a very wide thing, so what is defined as nerve damage and what is exactly happening, so it's not that the mesh itself is causing any problems. And what we realize is that in my own clinical trials and when we've seen and followed patients, I've not had any issues where there has been documented nerve damage, where the patient has pain running down the legs or numbness or things like that, nor has it been reported in the literature, nor has it been -- you know, when I review with my physician colleagues we have never seen that. So it's just not only what my own clinical trial, it's generally accepted that the mesh itself does not cause nerve damage.

Q. Okay. And you don't believe that mesh can cause nerve innervation, that the mesh can trap nerves and cause nerve damage?

MR. WALKER: Object to form.

THE WITNESS: There is no documentation like that in the literature.

MR. WALKER: And, again, when you said mesh, were you referring to Prolift and Prolift+M?

MR. WOOL: Yes.

BY MR. WOOL:

Q. Okay.

MR. WALKER: Want to take a break?

MR. WOOL: Yes, I can take a quick break.

(A recess was taken from 1:27 a.m. to 1:38 a.m.)

BY MR. WOOL:

Q. So, Doctor, I want to go back briefly just to the possible complications associated with either the Prolift or Prolift+M. Is erosion a possible complication for let's start with the Prolift?

A. So when -- again, I would just like to clarify, erosion is where the mesh is protruding into the neighboring viscus, is it exposure, exposure is where the mesh is protruding into the vagina.

Q. Okay. So let's start with protruding into the neighboring viscus.

A. So erosion.

Q. Yes.

A. So if there is -- you know, the mesh is just placed as it is. What I believe is that a lot depends upon the surgical technique. So if the surgical technique involves where the mesh is not placed appropriately, then the mesh could penetrate, could erode, could go into the organ, especially if it is thin. You know, sometimes when you open up the vagina and you're looking at the bladder, many a times that the bladder wall looks very thin. In fact, after I have done the surgery, whether with or without mesh, when I look inside the bladder, you may see a little bruising of the bladder wall, and that is because the wall of the bladder with prolonged prolapse could be extremely thinned out. And if that is so, when you lay the mesh, if it's a thinned out bladder wall, just because you dissect it in that area, that itself could lead to devascularization, and because of devascularization, that particular bladder wall can weaken and break down, and then it may look as though this mesh is protruding into the vagina. So it's a factor of several things.

One, the main reason why a mesh is used because of attenuation of the fascial tissue, so the tissues are very weak. Number two is if the bladder

wall is also so thin, then if you're placing it and operating in that area, that itself can cause blood vessel damage or devascularization, and that may look as though it's eroding. So I don't think personally, in my opinion, the mesh does not go into the bladder and erode in so that what an erosion is, so it's not, in other words, it's not an active process of the mesh doing it. It's more about the anatomy, what happens during the surgery, and, also, the technique, how was it placed? You know, was it placed very close to the bladder? Was it actually in the bladder during the placement, and was that missed, and then it looks, oh, it eroded afterwards, but actually it had already gone into the bladder during the placement.

Q. So it's a surgical error?

A. It could be that or it could be because of the -- what happens afterwards, because how the anatomy was. As I mentioned, literally and sometimes when you're just touching the bladder and moving the bladder, that can cause bruising of the bladder from the inside. If you're looking at the bladder -- so, in other words, after I finished the repair and everything has gone great, when I look inside the bladder you can see the bladder looking bruised. That's because the wall is so

thin, and that's why this is prolapsing out, because there is really no support tissue between the bladder and the vagina. See, when you have that thick support tissue, then the bladder is cushioned, but if there is no support tissue and the mesh is like right against the bladder, and if that wall is already weak and decides to break down, that looks as though it's -- so it could be surgical technique, or it also could be the weakness of the tissues. What I believe is that the mesh does not itself actively erode into the bladder.

Q. Okay. And the same answer for the Prolift+M?

A. And for Prolift+M, and also the same answer for vaginal exposure. So, for example, vaginal exposure is the opposite where it is eroding into the bladder, here it is looking into the vagina, you know, so which is the main thing that is reported. If you look at under complications, one of the major complications that has been reported is mesh exposures. However, what I believe is that and what has been now understood is it all depends upon the healing. So no surgeon has had -- has done an operation and made an incision anywhere in the body and never have that incision separate out at least a little bit. In abdominal wall it's called wound separation, which is very common. If you ask any

surgeon who has done a laparotomy, almost all surgeons have had some extent of wound separation. That is a healing process. It's -- if the vagina somehow decides not to heal and opens up, then the mesh can be seen, and that's mesh exposure. So the mesh is laid where it is.

So, again, here it could be healing process, which is a patient micro environment or it could be a surgical error where it may not have been placed deep enough, it may have been placed superficial, or the surgeon may have placed it correctly but the vagina was just too thin, which is the micro environment of where it's been placed. So those are the patient factors. So it's not -- so what I believe is it's not specific to the mesh, Prolift or Prolift+M. That does not cut through; it is overall, you know, the patient factors and the surgical technique.

Q. So let's just focus on one of those processes of erosion that you mentioned, the failure of the healing process. Now, in that type of situation where erosion is caused by a failure of the healing process, would you expect to see erosion happen fairly soon after surgery?

A. It varies. So typically if it is more at the incision site, then it could be there, but if it is over time, suppose if there is vaginal atrophy happening because

the patient is postmenopausal, and if it's happening over time, then it could manifest later on. So it doesn't have to be immediately thereafter.

Q. So if I'm understanding you correctly, the wound site atrophies over time?

A. The wound does heal, so the incision may have healed, so you could have the exposure in the vagina, for example, at different areas. Number one, it could be at the site of incision or maybe somewhere else. At the site of incision typically should happen while it's healing. But if it's anywhere else, it could be the thinning of the wall of the vagina, which could lead to eventually, you know, the mesh getting exposed.

Q. Okay. And so with the thinning of the wall of the vagina leading to exposure, if I'm understanding this correctly, the wall itself would have thinned on its own and the mesh is essentially just remaining in place?

A. Correct.

Q. So the mesh is static and the vagina is thinning, and that's what causes the exposure, correct?

A. Yes.

Q. I just want to make sure I'm understanding you.

A. However, most of the exposures do happen in the immediate postoperative period. In fact, most of the

papers that are published on mesh exposure do state that, you know, they have happened within the first year, so it's not that it's going on delayed, though it has been reported in the literature that you may get delayed exposure, but most of the exposures if they were to happen, they would happen within the first 12 months, if not immediately postoperatively.

Q. And exposures happening in the first 12 months, do those tend to happen at the wound site?

A. Most of them are at the wound site, but some could be at a different area of the vagina, also.

Q. And if it's not at the wound site, would you explain that by thinning of the vaginal wall?

A. Yes.

Q. Okay. And outside of menopause, what factors cause the vaginal wall to thin?

A. So let's look at two factors, one is a patient factor, second is the surgeon factor. From the patient factor, one is the extent of the prolapse, because the larger the prolapse is, the larger it has been outside, the more it has got what is known as decubitus ulcers, and these basically make the vaginal wall fragile and more vulnerable to healing.

Second is has she had any prior surgeries, and

prior surgeries, that means it's not well vascularized because there's usually scar tissue with any surgery, and that decreases the vascularity, less vascularity, the increased risk of breakdown.

Third is menopausal status, and that again is because of vaginal atrophy and, also, decreased blood supply.

These -- and then, fourth, are other factors which lead to vascular insufficiency in the vagina such as smoking, diabetic vasculopathy from diabetes, these are two main factors, and, of course, besides menopause.

So those are the main patient factors.

Then you look at the surgeon factors is, number one, did the surgeon keep the vaginal wall thick as described in the Prolift monograph, you know, the full thickness vaginal dissection, was that performed? If they did the full thickness vaginal dissection, then you're less likely to have that problem.

Number 2, did she form a hematoma inside? She may have had some blood collection. Did it collect, and did that cause the incision to open up?

Number 3, did the patient get an infection postoperatively?

So these are the different factors that could

result in exposure in the vagina.

Q. Okay.

A. And these are completely independent of the mesh.

Q. Okay. Switching gears, this is probably a little bit easier, so there are three Prolift kits; correct?

A. Yes.

Q. Okay. What are the three kits?

A. The anterior kit, the posterior kit, and the combined kit.

Q. And will you describe everything that's included with the kit.

A. It's been a long time that I've used it, but it's -- anterior has the anterior mesh and it has got the trocars to put it in, along with the mesh retrieval loops, so same thing posterior, as the posterior mesh has the trocars for delivery and the mesh retrieval loops, and the combined has it all together, so the anterior and posterior are in one unit, one whole mesh piece, and then you have the trocars for the anterior, the trocars for the posterior, and the mesh retrieval loops.

Q. Okay. And can you just briefly describe the implantation process generally.

MR. WALKER: For Prolift?

MR. WOOL: Yes, for Prolift.

THE WITNESS: So, first of all, it's -- I'll be brief, I won't go into whole -- you'll dissect the vagina after proper hydrodissection, so the key is there are certain steps that should be followed. Most important thing is that let's say suppose if I'm putting in a mesh right now anteriorly, I would dissect after proper hydrodissection. What that means, proper hydrodissection meaning that you're putting in this water, fluid, which could be containing a vasoconstrictor agent such as epinephrine or vasopressin. I use Lidocaine with epinephrine. I use quarter percent Lidocaine with 1 in 400,000 epinephrine. I inject into this space, what's called a vesicovaginal space. The way you know that you're in the right plane is because you will not see blanching of the vaginal mucosa, means now you know that you're leaving that vaginal epithelium completely intact and you're going in between the bladder and the vagina. Once that hydro-dissection is done, once you make an incision, you open up the vaginal walls, you dissect sharply into the paravaginal spaces. And once I get into the paravaginal space, then what I do is I use a headlight so I know exactly I'm getting into the paravaginal space, I put my

fingers in, and then I make the incisions on the outside for the passage of the trocars. So one is a superficial trocar, the other is the deep trocar. One comes out at the junction of the superior ramus of the pubis and the body of the pubis. The other one just comes out a centimeter above the ischial spine. So these are the two trocars that come out anteriorly. The mesh retrieval loops are inserted, and the mesh arms are pulled up.

The key thing the monograph alludes to is that initially when the total vaginal mesh group put this up, it was this was what was done. Just as you mentioned, the Information For Use, why as clinicians we just don't look at it and consider it gospel truth, because since then we have modified, we want to make sure it's properly placed, so what the monograph alludes to is that we now take a stitch on the cervix, we attach the mesh to the cervix proximally and maybe distally at the bladder neck so as to -- so the mesh will lay nice and flat. And once we know that the mesh is nice and flat, looks good, then the vagina is essentially closed under it. So that essentially is the anterior.

Similarly, we do it posteriorly, the posterior vaginal mucosa is opened -- you want me to continue with

this?

BY MR. WOOL:

Q. Yes.

A. So the rectum is dissected off the vagina. We get into what is known as the pararectal spaces. And then I put my fingers on the sacrospinous ligament, I get what is called a Briesky, B-r-i-e-s-k-y Navratel, N-a-v-r-a-t-e-l retractors, I look at the sacrospinous ligament, my headlight helps me identify it, put two fingers on top of the sacrospinous ligament, and that 3 centimeters lateral and inferior or posterior to the anus and make an incision which is about 3 to 4 millimeters after injecting local. I put the trocar in. As I'm putting the trocar in I guide it. Now, this is important, as you mentioned nerve injury, if it is done correctly, the pudendal nerves are behind the ischial spine or close by. It is critical to go 2 fingerbreadths medial, two fingerbreadths medial to the ischial spine, and then with the trocar should come out through the sacrospinous ligament. And once it emerges through the meat of the ligament, not behind it, because if the surgical technique goes in front of it, that's not good support, you're just going to the levator ani. And that's -- the IVS tunneler was doing that. If it

goes behind it, it could get the inferior gluteal nerve, and that can cause pain. And, therefore, it has to go through the meat of that sacrospinous ligament.

Once it's there, the mesh retrieval loop is inserted, loop is pulled out, the trocar is -- or the needle is removed, we put the mesh arm on each side, pull the mesh arms out, make sure the mesh lays flat, it could be attached to the cervix with a prolene thread or laterally to the uterosacral ligaments at the top, and at the bottom it's anchored to the pubococcygeus muscle through a simple little prolene suture. This is so that the mesh lays nice and flat on top of the rectum.

Sometimes I would -- may put the rectal fascia together, you know, sometimes I don't. In the front I don't put the fascia together. Here I may do a little bit of fascial plication at the bottom, then put the mesh on and then close the vagina.

BY MR. WOOL:

Q. Okay. So you described using two fingers to measure the distance from the pudendal nerve. Is the pudendal nerve located in the same anatomical position in all women?

A. There is some variation which could be about a centimeter variation, I believe, and, in fact, I was just doing an ultrasound study to see where it was,

because we wanted to do a pudendal nerve block, and it could be a variation where maybe about a centimeter medial. So most recommendations if you go two fingerbreadths medial, you should be able to avoid the nerve.

Q. Okay. Does the Prolift IFU indicate how to place the mesh tension free?

MR. WALKER: Feel free to refer to it if you need to.

THE WITNESS: Okay, so let's see, I think the key, as I mentioned, once we read this, it's ultimately, you know, what we do, and that is -- I would really count more on the monograph, and I think most of my colleagues when we used to go to the summit, they would count on the monograph more than the IFU. So let's see, where would that be.

MR. WALKER: And if you can't recall offhand, that's fine.

THE WITNESS: Well, I don't know if it specifically states that, I don't see it specifically but -- they do mention to lay -- if the sutures are placed -- but I don't know if they specifically state that.

BY MR. WOOL:

Q. How would you define tension free?

A. You know, it is a very interesting way to say that because there is -- it's basically just laying it without tacking it as such, so that's what it means. So what is done is that when you lay it, you know, if you -- we do tack it to the side, but it's not like some pulling across, so that word has changed. For example, the way I do it, I don't think I could call it completely, I don't say -- it's -- tension free is where it's placed without tension, let's put it -- let me say that, so tension free placed without tension, but it doesn't mean that it's placed without tacking sutures.

Q. Okay. Does the Prolift IFU indicate that patients may need to have multiple surgeries or operations to treat complications?

MR. WALKER: Object to form.

THE WITNESS: I'm not sure of that.

BY MR. WOOL:

Q. Does the IFU indicate that entire mesh removal may not be possible?

MR. WALKER: Object to form.

THE WITNESS: I don't think that it's up to IFU, it's up to mainly physicians to figure out what has

to be done.

BY MR. WOOL:

Q. Okay. Does the IFU indicate that mesh can cause chronic or severe pain?

MR. WALKER: Object to form.

THE WITNESS: It does say nerve damage, yes, it does.

BY MR. WOOL:

Q. Okay. Does it say that the nerve damage can be permanent?

MR. WALKER: Object to form.

THE WITNESS: There is nobody who can say "yes" or "no." See, this is -- it's very subjective, you know, what happens afterwards clinically is what's relevant, and in my practice I've never seen Prolift ever cause nerve damage which I've even temporarily had a problem with.

BY MR. WOOL:

Q. Does the IFU indicate that the Prolift can cause recurrent urinary tract infections?

MR. WALKER: Object to form.

THE WITNESS: The IFU, it's -- ultimately it's up to -- most of -- what you're asking are clinical questions which are determined by clinical application,

so when we use this and what happens in clinical literature, clinical data, and same thing what is published, what is written on there. So mesh never -- has not been documented cause a recurrent urinary tract infections, and I have in my experience never seen a recurrent urinary tract infections because of mesh.

Q. Okay. And is the Prolift currently available in the market today?

A. The Gynemesh is, but the Prolift system is not.

Q. Okay. Same question for the Prolift+M?

A. It's not available. The Ultrapro is, but the Prolift+M is not. So the mesh is -- I believe it's -- I'm not sure, though.

Q. And do you know when it was removed from the market?

A. I don't recall exactly.

Q. Do you know when the Prolift+M was removed from the market?

A. I believe the same time, but I don't know when.

Q. Do you know why the products were removed from the market?

A. Yes.

Q. Both the Prolift and the Prolift+M?

A. Yes.

Q. Why is that?

MR. WALKER: Object to form.

THE WITNESS: And I know this very well because I was at that time using Prolift+M and was very happy with it. Apparently, you know, at that time, you know, we had -- when the physicians interacted with Piet Hinoul, he was the medical director, H-i-n-o-u-l, first name P-i-e-t, he was the medical director, and he went to the FDA when FDA was mandating postmarket analysis studies, and he went to them and he said we have had enough clinical trials we've already done, and these are robust clinical trials that have been performed, level 1 evidence with randomized clinical trials. So Prolift and Prolift+M have been used in thousands of women with very good results being published, very strong papers with level 1 evidence. So we have done our due diligence, and I don't see why we should be subject to like some others who may not have done that. And FDA mandated that they had to do it.

So there was -- clinical evidence was absolutely crystal clear amongst the physicians and the company that it is a phenomenal product. It did great for improving women's pelvic health, and financially, you know, the decision was made that it's not -- they should not be doing these clinical trials, because they

had already done it, so it was more of a financial decision, it was made evident to most of the physicians who were doing it, because we were very upset as to why such a good product was being taken off the market when it was doing phenomenal in our patients. Now, almost all the physicians were livid when this happened, because it was -- it's an excellent product and it was taken away from our women, our patients, but it was a financial decision that Johnson & Johnson made.

BY MR. WOOL:

Q. Okay. Now, what is the difference between the Prolift and the Prolift+M kit?

A. I don't think there is any difference.

Q. So the only difference is the mesh that's involved?

A. Correct.

Q. And the Prolift+M has the Ultrapro mesh?

A. That is correct.

Q. Aside from that, the Instructions For Use are the same, to the best of your knowledge?

A. To the best of my knowledge, I think so, and there may be some more alteration maybe, but overall is the same, at least from a physician standpoint is the same.

Q. Okay. And the real, the only real difference is the absorbable Monocryl portion of the mesh?

A. And I believe they lengthened the posterior mesh a little bit, they widened it.
Q. And what's the purpose of the Monocryl fiber?
A. The Monocryl polyglecaprone 25, it is a material which is monofilament vicryl. The advantage of being is that you have a monofilament polypropylene, so monofilament is single filament, not multi-filament, so concern is a multi-filament thread/mesh could possibly harbor more infections because you have small pore size if it's multi-filament where as monofilament would not. So then they did not want to use vicryl, so they went with monofilament vicryl, which is Monocryl, and the Monocryl disappears over time. The thinking process at that time of the engineers is that if the fibroblasts and the encapsulation, you know, the classic foreign body reaction I mentioned sometime back, as that is happening, once it goes through its process and by the time it goes from acute inflammation to chronic inflammation to, you know, granulation tissue, foreign body reaction, to encapsulation, that fibroblast, so by the time the fibroblasts are actually coming in and scar tissue is forming, the Monocryl is getting dissolved. So hopefully it just stays there until it's required, and then it goes away.

That would hopefully increase pore size, and it does, it decreases the size of the mesh, so the pore size went up from, I believe, 2.4 to 4.1 millimeters, and the weight went down from 51 to 30 grams per centimeter. So that may have some role. If you have less mesh left behind, could that be beneficial; that was the premise.

Q. Okay. And are you aware if Ethicon performed any premarket clinical testing on the Ultrapro mesh?

A. I am not aware.

Q. Not aware. And do you have an opinion as to whether or not the Ultrapro mesh has a foreign body reaction?

A. Every foreign body has a foreign body reaction, so Ultrapro mesh also should have a foreign body reaction which is selfsustained.

Q. Do you have an opinion as to whether the Ultrapro mesh leads to an increased foreign body reaction?

A. I don't think it should make a difference.

MR. WALKER: I'm sorry, when you said increased, relative to what?

MR. WOOL: I'm sorry, relative to the Gynemesh.

THE WITNESS: To Gynemesh PS.

BY MR. WOOL:

Q. Right. So to clarify, do you have an opinion on whether or not either -- do you have an opinion whether or not the Ultrapro mesh causes a different or a more severe foreign body reaction than the Gynemesh?

A. No, I don't.

Q. Okay.

A. Gynemesh PS.

Q. Yes, Gynemesh PS. So do you have an opinion as to whether the Ultrapro mesh has any sort of different reaction as it relates to inflammation than the Gynemesh PS?

A. No. I have an opinion that there is no difference.

Q. Okay. So I'm going to ask you basically some of the same questions I asked you about on the warnings on the Prolift IFU -- sorry, yeah, the Prolift IFU.

Does the Prolift+M IFU indicate that patients may need to have had multiple surgical procedures to treat complications related to the mesh product?

MR. WALKER: Object to form.

THE WITNESS: I don't know if that is in the IFU, but that's something that the clinicians, that we would be able to decide and determine from literature, and knowing from what our own experience is, and I have

never had that happen, so I have never had to go in for a Prolift+M and do repeated surgeries for anything for that matter.

BY MR. WOOL:

Q. Does the Prolift+M IFU indicate that multiple or repeat surgical procedures may still not be able to correct the complications related to the mesh product?

MR. WALKER: Object to form.

THE WITNESS: See, I think my opinion's mainly based not that much on the IFU. My opinion is based upon my experience and my dealing with my colleagues and discussing with my colleagues and the medical literature, so from that standpoint it's not been documented.

BY MR. WOOL:

Q. Does the Prolift+M IFU indicate that complete mesh removal may not be possible?

MR. WALKER: Object to form.

THE WITNESS: It's, again, the same answer. It's mainly from my experience what I can tell you, I've never had to remove a mesh, myself personally, I've never had to remove a mesh completely, I've never had to explant a mesh, and very few of my colleagues had to totally explant a mesh, and especially -- and the

medical literature states the same. That if it is in fact -- in fact, the interesting part is even if a mesh is exposed in the vagina and it is now open to the micro-environment of the vagina which has its own bacteria, despite that, it can be expectantly managed. So not all exposed meshes have to be cut out. So, in other words, if there was a major concern with infection or inflammation, we would be trying to cut this exposed mesh out because it is exposed in the vagina, but more than -- no matter which study you look at, whether it is the Abed, A-b-e-d, study, which is the meta-analysis of complications or in our group you can see that more than 50 percent of the exposed mesh are managed expectantly without surgical removal, so an explant is almost unnecessary in most cases.

BY MR. WOOL:

Q. Okay. Does the Prolift+M IFU instruct how to place the mesh tension free?

MR. WALKER: Object to form.

THE WITNESS: It states how to do it, and then the monogram is the main important document that goes and explains how this should be placed. But more importantly is the -- ultimately I think what happens is like with any other field, it depends upon the surgeon

and how the surgeon eventually figures this out and what is the best technique to do and based upon their experience.

So what I can tell you is from my experience, I've realized how best to place it, what I need to do, what are the key things, and then when we discuss as what -- so monograph is a consortium of physicians, experienced doctors who came together and put this information for others to read and as guidelines and more guidelines from doctors' perspective, as a surgeon's perspective, that's something that we follow.

BY MR. WOOL:

Q. The monogram?

A. The monogram.

Q. Let's see. Does the Prolift+M IFU indicate that the Prolift may cause chronic dyspareunia?

MR. WALKER: Object to form.

THE WITNESS: I don't believe that mesh causes dyspareunia at all. It's the surgical process that is there, so I don't -- would not look for it.

BY MR. WOOL:

Q. Okay. Does the IFU for the Prolift+M indicate that the mesh can cause permanent or severe never damage?

MR. WALKER: Object to form.

THE WITNESS: A mesh does not cause nerve damage, so it should not be indicating such. It does mention that potential risk of nerve damage from the procedure, which is the vaginal procedure, but the mesh itself does not cause nerve damage.

BY MR. WOOL:

Q. Okay. Does the Prolift+M IFU indicate that the mesh can cause chronic or recurrent urinary tract infections?

MR. WALKER: Object to form.

THE WITNESS: It is not up to the IFU to state, I mean it's for us to determine, so it is -- so what we have seen, it doesn't cause, I've never seen Prolift+M mesh not as it is reported in literature. So the fact of the matter is clinically what is relevant, which is my experience, what's out of the literature, and what is reviewed by my colleagues, is it does not cause recurrent urinary tract infections.

BY MR. WOOL:

Q. So to be clear, the IFU does not indicate that or you're saying --

A. It's what is important for me to base my opinion is my experience and the experience of what has been out in the literature. So there is literally -- and as I have mentioned, the key thing is putting things in

perspective, what is the incidence, what's the likelihood of that happening? And that is -- you know, this report would not -- and we just look at it what are -- but that is intuitive, that is something that a surgeon understands, that when you operate in the vagina, you know, can this happen? So there is no -- the mesh per se does not cause bladder infections, just operating in the vagina, can it cause bladder infections? Actually not. I mean if you think about it, a patient has vaginal prolapse. The bladder is hanging outside. So now it's hanging outside. So she is retaining urine because she can't empty. Because she is retaining urine, she gets bladder infections. You put the vagina back inside, the bladder goes inside, now she can empty her bladder better, she's less likely to get bladder infections. So what I believe is Prolift/Prolift+M mesh reconstruction procedure when done in patients with large anterior vaginal wall prolapse will actually decrease the incidence of bladder infections especially by eliminating the stagnant urine and retention.

Q. So I understand your statement that you think that that warning would be irrelevant, but I think my question's a little bit more simple, which is simply does the IFU

warn of chronic or recurrent urinary tract infections?

MR. WALKER: Object to form.

THE WITNESS: See, I would tell you clinically, so from the clinical standpoint, I think it doesn't cause it; it, in fact, helps it. That's more relevant, you know, than what my findings or what's out there in literature, what has been published, and no where would you say that urinary tract infections are increased by placement of a mesh or doing this surgical procedure. Even if I -- I think -- I don't think even native tissue repair states that there is increased -- would also cause bladder infections.

Q. Okay. So, again, I'm not asking for your opinion on whether or not -- either -- whether or not the Prolift+M causes chronic or recurrent urinary tract infections or whether it's relevant to warn against. I'm only asking whether the IFU warns against chronic or recurring urinary tract infections.

A. But, see, what's more relevant is that IFU is just a document. It just states whether -- yes or no, you know, so I don't see a specific word frequent bladder infections in the IFU.

Q. Okay. Can I ask how much time we're at?

(An off-the-record discussion was held.)

BY MR. WOOL:

Q. You mentioned that you follow the monogram and that you depart from the actual Instructions For Use?

MR. WALKER: Object to form, misstates his testimony.

BY MR. WOOL:

Q. Okay. So will you describe whether or not you follow the IFU, I guess, to the T for either the Prolift or the Prolift+M?

A. IFU --

MR. WALKER: Object to form.

THE WITNESS: If you ask most physicians, IFU is a document that they look at it, they read it, and they understand it. Then they ultimately -- their practice, what they do is determined by what happens with their peers, what are the colleagues teaching them, what happens when they go to the cadaver lab, what -- cadaver lab is not just about going and putting a mesh in the cadaver. It's a whole discussion. You know, the panel discussion that happens before that, where you look at your peers that you respect, and they tell you their experience, what is the science behind it, you learn all these things. That all is very important. Then you read literature what has been published on this

product. That is more important to physicians. It's almost akin to a manual that you get with a product, you know, whether you get your iPhone or anything else, you get instruction manual. Now, how many people actually go through the whole manual? So this is important as a guidance, but what we really count on is my colleagues and what we have experienced, if, let's say Prolift+M, and I have already used Prolift, so I know what to expect from the surgical standpoint, and I understand when I moved to Prolift+M, you know, did I look at the IFU? Yes, but was I reading it and memorizing it? No, because once I read it I understood it. Then what matters is what are the publications, what is happening? What is the clinical science that is coming out with this particular product and its application in the pelvic floor. And that has significant more relevance to my colleagues and to myself than the IFU so.

BY MR. WOOL:

Q. Do you think the IFU should change as the literature changes?

MR. WALKER: Object to form.

THE WITNESS: It's impossible for the IFU to keep all this literature. It's for us to understand what is happening, and then there are so many elements

to that. One is medical literature, that means you're reading what's published, then conferences, discussions, networking, and personal experiences. All those form the basis of a physician's decision to proceed in which manner. That is the crux. That is what we as surgeons and we as physicians go by. Ultimately, ultimately more than any of this is our patient. You know, the patients I've operated on, what does she come back and say? How has she been doing? What are the outcomes we are seeing? And if we see nothing but phenomenal outcomes, there's nothing else that can detract from that. It's ultimately the patients who matter.

BY MR. WOOL:

Q. So how does your own practice involving the Prolift differ from the IFU?

A. I don't think it differs. It's just that I go over that information with the patient in proper perspective. You know, the IFU has the information, it is proper, it has all the stuff that is there, but that's not for a patient. Like, for example, it may say nerve damage. The patient doesn't understand what's nerve damage. I have to explain what that means if at all it were to be relevant from the vagina surgical standpoint, not the mesh standpoint. So the way I would explain is I put

things more in perspective by giving them the likelihood of that happening. Now, that is more tangible to a person than just stating. That's the only difference I would say, the IFU is complete, it has the stuff, but it doesn't have what I would consider as -- you know, from when we talk to our patient, we tell them what is the likelihood of that happening, so that's the main difference.

Q. So I think I'm asking a slightly different question. I'm asking does your own surgical procedure differ from the IFU?

MR. WALKER: For which product?

MR. WOOL: For the Prolift.

THE WITNESS: The only -- when I used to do that, of course now it's not available, when I was doing that, the only difference is that it's similar to the monogram, and I would tack it to the cervix. I don't think the IFU states that you need to tack it to the cervix or put those side -- onto the muscle so that the mesh does not roll, it remains nice and flat. So that's where we evolve. And the beauty of the surgical technique is that we get better and better, you know, as we keep doing these cases, as we see our outcomes and our results.

BY MR. WOOL:

Q. Okay. And is your technique the same for the Prolift+M?

A. Yes.

Q. Okay. And does it differ in the same way for the Prolift+M IFU?

A. Yes.

Q. Okay. I think that's about it for me. Have anything?

MR. WALKER: I have nothing.

(The deposition was concluded at 2:17 p.m.)

CERTIFICATE OF NOTARY

STATE OF MICHIGAN)
) SS
COUNTY OF OAKLAND)

I, Laurel A. Frogner, Certified Shorthand Reporter, a Notary Public in and for the above county and state, do hereby certify that the above deposition was taken before me at the time and place hereinbefore set forth; that the witness was by me first duly sworn to testify to the truth, and nothing but the truth, that the foregoing questions asked and answers made by the witness were duly recorded by me stenographically and reduced to computer transcription; that this is a true, full and correct transcript of my stenographic notes so taken; and that I am not related to, nor of counsel to either party nor interested in the event of this cause.

Laurel A. Frogner, CSR-2495, RMR, CRR
Notary Public,
Oakland County, Michigan
My Commission expires: 4-22-2022

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

SALIL KHANDWALA, M.D. DATE

Subscribed and sworn to before me this

_____ day of _____, 20____.

My commission expires:_____

_____

Notary Public